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**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

NORMAN JOHNSON, derivatively on  
behalf of OUTSET MEDICAL, INC.,

Plaintiff,

v.

LESLIE TRIGG, NABEEL AHMED,  
REBECCA CHAMBERS, THOMAS J.  
CARELLA, KAREN DREXLER, D. KEITH  
GROSSMAN, PATRICK T. HACKETT,  
JIM HINRICHS, DALE E. JONES, ALI  
OSMAN, ANDREA SAIA, and  
CATHERINE SZYMAN,

Defendants,

and

OUTSET MEDICAL, INC,

Nominal Defendant.

Case No.

**VERIFIED SHAREHOLDER  
DERIVATIVE COMPLAINT**

DEMAND FOR JURY TRIAL

Plaintiff Norman Johnson ("Plaintiff"), by and through his undersigned attorneys, brings  
this Verified Shareholder Derivative Complaint, for the benefit of Nominal Defendant Outset

1 Medical, Inc. (“Outset” or the “Company”), against Defendants Leslie Trigg (“Trigg”), Nabeel  
2 Ahmed (“Ahmed”), Rebecca Chambers (“Chambers”), Thomas J. Carella (“Carella”), Karen  
3 Drexler (“Drexler”), D. Keith Grossman (“Grossman”), Patrick T. Hackett (“Hackett”), Jim  
4 Hinrichs (“Hinrichs”), Dale E. Jones (“Jones”), Ali Osman (“Osman”), Andrea Saia (“Saia”), and  
5 Catherine Szyman (“Szyman”) (collectively, the “Individual Defendants” and with Outset,  
6 “Defendants), to remedy the Individual Defendants’ breaches of fiduciary duties and violations  
7 of federal law as contained herein.

8 Plaintiff’s allegations are based upon personal knowledge as to himself and his own acts,  
9 and upon information and belief, based on the investigation of Plaintiff’s counsel, including a  
10 review of publicly available information, filings by Outset with the U.S. Securities and Exchange  
11 Commission (“SEC”), press releases, news reports, analyst reports, investor conference  
12 transcripts, publicly available filings in lawsuits including the securities class action *In re Outset*  
13 *Medical Inc. Securities Litigation*, No. 5:24-cv-06124-EJD (N.D. Cal.) (the “Securities Class  
14 Action”), and matters of public record. Plaintiff believes that substantial evidentiary support will  
15 exist for the allegations set forth herein after a reasonable opportunity for discovery.

### 16 **NATURE OF THE ACTION**

17 1. This is a shareholder derivative action brought on behalf of Outset against certain  
18 current and former officers and members of the Company’s Board of Directors (the “Board”) for  
19 breaches of their fiduciary duties and violations of the federal securities laws committed between  
20 September 15, 2020 and August 7, 2024, both dates inclusive (the “Relevant Period”).

21 2. Outset is a medical technology company with a mission of advancing kidney  
22 dialysis, which is the primary treatment for acute and chronic kidney failure.

23 3. The Company’s flagship product, the Tablo Hemodialysis System (“Tablo”), is an  
24 innovative dialysis machine that purifies tap water and facilitates the removal of toxins from the  
25 blood of patients with kidney failure.

26 4. Tablo has received clearance from the U.S. Food and Drug Administration  
27 (“FDA”) for use in hospital, clinic, and home settings.

1           5.       Tablo is not FDA-cleared for Continuous Renal Replacement Therapy (“CRRT”),  
2 a hospital-based treatment in which solute removal and fluid balance are managed continuously  
3 over a 24-hour period.

4           6.       In October 2022, Outset introduced the TabloCart with Prefiltration (“TabloCart”),  
5 a specialized accessory designed to enhance maneuverability and optimize water pre-filtration in  
6 environments with compromised water quality.

7           7.       Throughout the Relevant Period, the Individual Defendants touted that Tablo and  
8 TabloCart had proper FDA approval and the products’ sales were on track and driving the  
9 Company’s growth when, in reality, Tablo had not been cleared for CRRT by the FDA and  
10 TabloCart had not received the proper marketing authorization from the FDA.

11           8.       The truth began to emerge on July 7, 2023, when Outset announced that it had  
12 received a warning letter from the FDA (the “Warning Letter”) that asserted that certain materials  
13 “on the Company’s website promote continuously renal replacement therapy (CRRT), a modality  
14 outside of the current indications for the Tablo Hemodialysis System” and that Tablo Cart “requires  
15 prior 510(k) clearance for marketing authorization.”

16           9.       On this news, Outset’s stock price fell \$1.20 per share, to close at \$19.26 per share  
17 on July 10, 2023, the next trading day.

18           10.      On August 2, 2023, Outset issued a press release announcing that it was pausing  
19 the shipment of TabloCart pending 501(k) clearance from the FDA.

20           11.      On this news, Outset’s stock price fell \$1.97 per share, to close at \$17.39 per share  
21 on August 3, 2023.

22           12.      On October 12, 2023, Outset issued a press release reporting its preliminary  
23 quarter 2023 financial results, revealing that its revenue growth had been significantly affected  
24 by the Warning Letter.

25           13.      On this news, the Company’s stock price dropped by \$3.38 per share, to close at  
26 \$3.39 per share on October 13, 2023.

1           14. The truth fully emerged on August 7, 2024, when Outset issued a press release  
2 announcing its financial results for the second quarter of 2024, wherein the Company revealed  
3 that it significantly missed consensus estimates and was lowering its full-year 2042 guidance by  
4 \$39 million at the endpoint. The Company also revealed that it would be unable to achieve the  
5 previously forecasted post-approval sales ramp of TabloCart.

6           15. On this news, the Company's stock price dropped by \$2.33 per share, to close at  
7 \$1.07 per share on August 8, 2024.

8           16. While the Company's stock price was artificially inflated as a result of the  
9 Individual Defendants' false and misleading statements and omissions, certain of the Individual  
10 Defendants were unjustly enriched by engaging in insider sales.

11           17. As a result of the foregoing, two securities class actions were filed against the  
12 Company and Defendants Trigg, Ahmed, and Chambers in the United States District Court for  
13 the Northern District of California, which were subsequently consolidated into the Securities  
14 Class Action.

15           18. As a direct and proximate result of the Individual Defendants' misconduct, the  
16 Company has incurred significant damages, including the cost of defending and potentially  
17 paying class-wide damages in the Securities Class Action, and reputational harm and the loss of  
18 goodwill with investors.

19           19. In light of the breaches of fiduciary duty by the Individual Defendants, most of  
20 whom are the Company's current directors, their collective engagement in fraud, the substantial  
21 likelihood of the directors' liability in this derivative action and the Securities Class Action, and  
22 the Individual Defendants longstanding business and personal relationships with one another, the  
23 Individual Defendants cannot consider a demand to commence litigation on behalf of the  
24 Company against themselves and the other Individual Defendants with the requisite level of  
25 disinterestedness and independence.

**JURISDICTION AND VENUE**

20. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 14(a) of the Exchange Act (15 U.S.C. § 78n(a)(1)), Rule 14a-9 of the Exchange Act (17 C.F.R. § 240.14a-9), Section 10(b) of the Exchange Act (15 U.S.C. § 78j(b)) and Section 21D of the Exchange Act (15 U.S.C. § 78u-4(f)). Plaintiff's claims also raise a federal question pertaining to the claims made in the Securities Class Action based on violations of the Exchange Act.

21. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 USC. §1367(a).

22. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

23. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and Section 27(a) of the Exchange Act because Outset is headquartered in this District, Defendants have conducted business and received compensation in this District, Defendants' actions have had an effect in this District, and a substantial portion of the transactions and wrongs complained of herein occurred in this District.

**PARTIES**

24. Plaintiff is, and has been, a continuous shareholder of Outset at all relevant times.

25. Nominal Defendant Outset is a Delaware corporation with its principal executive offices located at 3052 Orchard Drive, San Jose, California, California 95134. Outset's common stock trades on the NASDAQ under the ticker symbol "OM."

26. Defendant Trigg has served as Outset's Chief Executive Officer ("CEO") since November 2013 and as Board Chair since 2022. According to the Company's annual proxy statements filed with the SEC, Defendant Trigg received, as compensation from the Company: \$2,796,160 for the 2020 Fiscal Year ("FY"); \$7,138,281 for the 2021 FY; \$4,128,283 for the 2022 FY; \$6,474,946 for the 2023 FY; and \$4,002,620 for the 2024 FY. According to the Company's 2024 Proxy Statement filed with the SEC on April 11, 2024 (the "April 2024 Proxy

Statement”), as of March 6, 2024, Defendant Trigg beneficially owned 1,052,324 shares of the Company’s total outstanding common stock. Defendant Trigg is named as a defendant in the Securities Class Action.

27. Defendant Ahmed has served as Outset’s Chief Financial Officer since August 2021. Prior to that, he joined Outset in May 2020 as Vice President, Controller, and also served as interim CFO from July 2021 through August 2021. According to the Company’s annual proxy statements filed with the SEC, Defendant Ahmed received, as compensation from the Company: \$420,805 for the 2020 FY; \$1,784,411 for the 2021 FY; \$1,752,268 for the 2022 FY; \$2,328,951 for the 2023 FY; and \$1,791,014 for the 2024 FY. According to April 2024 Proxy Statement, as of March 6, 2024, Defendant Ahmed beneficially owned 81,334 shares of the Company’s total outstanding common stock. Defendant Ahmer is named as a defendant in the Securities Class Action.

28. Defendant Chambers served as the Company’s Chief Financial Officer (“CFO”) from June 2019 until she resigned in July 2021. According to the Company’s annual proxy statements filed with the SEC, Defendant Chambers received, as compensation from the Company: \$2,424,674 for the 2020 FY; and \$1,621,853 for the 2021 FY. Defendant Chambers is named as a defendant in the Securities Class Action.

29. Defendant Carella served as member of the Board from April 2019 until January 2021. According to the Company’s annual proxy statements filed with the SEC, Defendant Carella received, as compensation from the Company: \$30,000 for the 2020 FY; and \$1,333 for the 2021 FY.

30. Defendant Drexler has served as a member of the Board since January 2021 and serves as a member of the Compensation Committee. According to the Company’s annual proxy statements filed with the SEC, Defendant Drexler received, as compensation from the Company: \$474,565 for the 2021 FY; \$214,984 for the 2022 FY; \$224,171 for the 2023 FY; and \$156,875 for the 2024 FY. According to April 2024 Proxy Statement, as of March 6, 2024, Defendant Drexler beneficially owned 15,551 shares of the Company’s total outstanding common stock.

1           31. Defendant Grossman has served as member of the Board since April 2014 and as  
2 the Lead Independent Director of the Board since February 2022. Prior to that, Defendant  
3 Grossman served as Chairman of the Board from April 2014 to February 2022. Defendant  
4 Grossman also serves as a member of the Compensation Committee and the Corporate  
5 Governance Committee. According to the Company's annual proxy statements filed with the  
6 SEC, Defendant Grossman received, as compensation from the Company: \$226,409 for the 2020  
7 FY; \$249,999 for the 2021 FY; \$249,984 for the 2022 FY; \$264,995 for the 2023 FY; and  
8 \$200,000 for the 2024 FY. According to April 2024 Proxy Statement, as of March 6, 2024,  
9 Defendant Grossman beneficially owned 299,856 shares of the Company's total outstanding  
10 common stock.

11           32. Defendant Hackett has served as a member of the Board since May 2019.  
12 Defendant Hackett also serves as Chair of the Corporate Governance Committee and as a member  
13 of the Audit Committee. According to the Company's annual proxy statements filed with the  
14 SEC, Defendant Hackett received, as compensation from the Company: \$181,691 for the 2020  
15 FY; \$209,999 for the 2021 FY; \$209,984 for the 2022 FY; \$224,995 for the 2023 FY; and  
16 \$160,571 for the 2024 FY. According to April 2024 Proxy Statement, as of March 6, 2024,  
17 Defendant Hackett beneficially owned 48,142 shares of the Company's total outstanding common  
18 stock.

19           33. Defendant Jones has served as a member of the Board since April 2022. Defendant  
20 Jones also serves as Chair of the Compensation Committee. According to the Company's annual  
21 proxy statements filed with the SEC, Defendant Jones received, as compensation from the  
22 Company: \$447,048 for the 2022 FY; \$220,819 for the 2023 FY; and \$160,000 for the 2024 FY.  
23 According to April 2024 Proxy Statement, as of March 6, 2024, Defendant Jones beneficially  
24 owned 11,120 shares of the Company's total outstanding common stock.

25           34. Defendant Osman served as member of the Board from February 2020 until March  
26 2021. According to the Company's annual proxy statements filed with the SEC, Defendant  
27  
28

1 Osman received, as compensation from the Company: \$32,500 for the 2020 FY; and \$16,250 for  
2 the 2021 FY.

3 35. Defendant Saia has served as a member of the Board since March 2021. Defendant  
4 Saia also serves as a member of the Audit Committee. According to the Company's annual proxy  
5 statements filed with the SEC, Defendant Saia received, as compensation from the Company:  
6 \$451,197 for the 2021 FY; \$199,984 for the 2022 FY; \$214,995 for the 2023 FY; and \$150,000  
7 for the 2024 FY. According to April 2024 Proxy Statement, as of March 6, 2024, Defendant Saia  
8 beneficially owned 15,211 shares of the Company's total outstanding common stock.

9 36. Defendant Szyman served as a member of the Board from May 2021 until her  
10 resignation in March 2024. According to the Company's annual proxy statements filed with the  
11 SEC, Defendant Szyman received, as compensation from the Company: \$443,244 for the 2021  
12 FY; \$199,984 for the 2022 FY; \$159,995 for the 2023 FY; and \$9,973 for the 2024 FY.

13 37. Defendant Hinrichs served as a member of the Board from February 2020 until his  
14 resignation in August 2024. According to the Company's annual proxy statements filed with the  
15 SEC, Defendant Hinrichs received, as compensation from the Company: \$425,842 for the 2020  
16 FY; \$209,999 for the 2021 FY; \$209,984 for the 2022 FY; \$224,995 for the 2023 FY; and  
17 \$135,625 for the 2024 FY. According to April 2024 Proxy Statement, as of March 6, 2024,  
18 Defendant Hackett beneficially owned 142,604 shares of the Company's total outstanding  
19 common stock.

20 **FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS**

21 38. By reason of their positions as officers, directors, and/or fiduciaries of Outset and  
22 because of their ability to control the business and corporate affairs of Outset, the Individual  
23 Defendants owed the Company and its shareholders the fiduciary obligations of trust, loyalty,  
24 good faith, and due care, and were and are required to use their utmost ability to control and  
25 manage the Company in a fair, just, honest, and equitable manner. The Individual Defendants  
26 were and are required to act in furtherance of the best interests of the Company and its  
27 shareholders.

1           39. Each director and officer of the Company owes to the Company and its  
2 shareholders the fiduciary duty to exercise good faith and diligence in the administration of the  
3 affairs of the Company and in the use and preservation of its property and assets, as well as the  
4 highest obligations of fair dealing.

5           40. As officers and/or directors of a publicly held company, the Individual Defendants  
6 had a duty to promptly disseminate accurate and truthful information regarding the Company's  
7 operations, finances, financial condition, and present and future business prospects so that the  
8 market price of the Company's stock would be based on truthful and accurate information.

9           41. The Individual Defendants, because of their positions of control and authority as  
10 directors and/or officers of the Company, were able to and did, directly and/or indirectly, exercise  
11 control over the wrongful acts complained of herein, as well as the contents of the various public  
12 statements issued by the Company. Because of their advisory, executive, managerial and  
13 directorial positions with the Company, each of the Defendants had access to adverse non-public  
14 information about the financial condition, operations, sales and marketing practices, and improper  
15 representations of the Company.

16           42. To discharge their duties, the officers and directors of the Company were required  
17 to exercise reasonable and prudent supervision over the management, policies, practices, and  
18 controls of the financial affairs of the Company. By virtue of such duties, the officers and directors  
19 of the Company were required to, among other things:

20           (a) ensure that the Company was operated in a diligent, honest, and prudent  
21 manner in accordance with the laws and regulations of Delaware and the United States, and  
22 pursuant to Outset's own Code of Business Conduct and Ethics (the "Code of Conduct");

23           (b) conduct the affairs of the Company in an efficient, business-like manner  
24 so as to make it possible to provide the highest quality performance of its business, to avoid  
25 wasting the Company's assets, and to maximize the value of the Company's stock;

26           (c) remain informed as to how Outset conducted its operations, and, upon  
27 receipt of notice or information of imprudent or unsound conditions or practices, to make

1 reasonable inquiry in connection therewith, and to take steps to correct such conditions or  
2 practices;

3 (d) establish and maintain systematic and accurate records and reports of the  
4 business and internal affairs of Outset and procedures for the reporting of the business and internal  
5 affairs to the Board and to periodically investigate, or cause independent investigation to be made  
6 of, said reports and records;

7 (e) maintain, implement, and monitor an adequate and functioning system of  
8 internal legal, financial, and management controls, such that Outset's publicly disclosed financial  
9 information would be accurate;

10 (f) exercise reasonable control and supervision over the public statements  
11 made by the Company's officers and employees and any other reports or information that the  
12 Company was required by law to disseminate;

13 (g) refrain from unduly benefiting themselves and other Company insiders at  
14 the expense of the Company; and

15 (h) examine and evaluate any reports of examinations, audits, or other  
16 financial information concerning the financial affairs of the Company and to make full and  
17 accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set  
18 forth above.

19 43. Each Individual Defendant, by virtue of his or her position as a director and/or  
20 officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith,  
21 and the exercise of due care and diligence in the management and administration of the affairs of  
22 the Company, as well as in the use and preservation of its property and assets. The conduct of the  
23 Individual Defendants complained of herein involves a knowing and culpable violation of their  
24 obligations as directors and officers of the Company, the absence of good faith on their part, and  
25 a reckless disregard for their duties to the Company and its shareholders that the Individual  
26 Defendants were aware or should have been aware posed a risk of serious injury to the Company.

1           44. Each of the Individual Defendants owed to Outset and the shareholders the duty  
2 of loyalty requiring that each favor Outset's interest and that of its shareholders over their own  
3 while conducting the affairs of the Company and refrain from using their position, influence, or  
4 knowledge of the affairs of the Company to gain personal advantage.

5           45. The Individual Defendants, because of their positions of control and authority,  
6 were able to and did, directly or indirectly, exercise control over the wrongful acts complained of  
7 herein, as well as the contents of the various public statements issued by Outset.

8           46. At all times relevant hereto, the Individual Defendants were the agents of each  
9 other and of Outset and at all times acted within the course and scope of such agency.

10           **CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION**

11           47. In committing the wrongful acts alleged herein, the Individual Defendants have  
12 pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with  
13 and conspired with one another in furtherance of their wrongdoing. The Individual Defendants  
14 caused the Company to conceal the true facts as alleged herein. The Individual Defendants further  
15 aided and abetted and/or assisted each other in breaching their respective duties.

16           48. The purpose and effect of the conspiracy, common enterprise, and/or common  
17 course of conduct was, among other things, to facilitate and disguise the Individual Defendants'  
18 violations of law, including breaches of fiduciary duty and unjust enrichment.

19           49. The Individual Defendants accomplished their conspiracy, common enterprise,  
20 and/or common course of conduct by causing the Company, purposefully, recklessly, or  
21 negligently, to conceal material facts, to fail to correct such misrepresentations, and to violate  
22 applicable laws.

23           50. In furtherance of this plan, conspiracy, and course of conduct, the Individual  
24 Defendants collectively and individually took the actions set forth herein. Because the actions  
25 described herein occurred under the authority of the Board and the Company's senior  
26 management, each of the Individual Defendants, who are directors or officers of Outset, was a  
27

1 direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or  
2 common course of conduct complained of herein.

3 51. In taking such actions to substantially assist the commission of the wrongdoing  
4 complained of herein, each Individual Defendant acted with actual or constructive knowledge of  
5 the primary wrongdoing, either took direct part in, or substantially assisted the accomplishment  
6 of that wrongdoing, and was or should have been aware of his or her overall contribution to and  
7 furtherance of the wrongdoing. As such, each of the Individual Defendants aided and abetted and  
8 rendered substantial assistance in the wrongs complained of herein.

9 52. At all times relevant hereto, each of the Individual Defendants was the agent of  
10 each of the other Individual Defendants and of Outset and at all times acted within the course and  
11 scope of such agency.

### 12 **OUTSET'S CODE OF CONDUCT**

13 53. Outset's Code of Business Conduct and Ethics ("Code of Conduct") provides the  
14 following statement in the "Introduction" section, in relevant part:

15 Outset Medical, Inc. (the "Company" or "Outset") is committed to maintain the  
16 highest standards of business conduct and ethics. This Code of Business Conduct  
17 and Ethics (the "Code") reflects the business practices and principles of behavior  
18 that support this commitment. We expect every employee, officer and director of  
19 Outset to read and understand the Code and its application to the performance of  
his or her business responsibilities. References in the Code to employees are  
intended to cover officers and, as applicable, directors.

20 Officers, managers, and other supervisors are expected to develop in employees a  
21 sense of commitment to the spirit, as well as the letter of the Code. Supervisors are  
22 also expected to ensure that all agents and contractors conform to Code standards  
23 when working for or on behalf of Outset. Nothing in the Code alters the at-will  
employment policy of the Company.

24 The Code addresses conduct that is particularly important to proper dealings with  
25 the people and entities with whom we interact but reflects only a part of our  
26 commitment. From time to time, we may adopt additional policies and procedures  
with which our employees, officers and directors are expected to comply.  
However, it is the responsibility of each employee to apply common sense,

1 together with his or her own highest personal ethical standards, in making business  
2 decisions where there is no stated guideline in the Code.

3 54. In the section titled “Honest and Ethical Conduct,” the Code of Conduct states:

4 It is our policy to promote high standards of integrity by conducting our affairs in  
5 an honest and ethical manner. The integrity and reputation of Outset depends on  
6 the honesty, fairness and integrity brought to the job by each person associated  
7 with us. Unyielding personal integrity is the foundation of corporate integrity.

8 55. In a section titled “Legal Compliance,” the Code of Conduct states:

9 Obeying the law, both in letter and in spirit, is the foundation of this Code. Our  
10 success depends upon each employee’s operating within legal guidelines and  
11 cooperating with local, national and international authorities. We expect  
12 employees to understand the legal and regulatory requirements applicable to their  
13 business units and areas of responsibility. We hold periodic training sessions to  
14 ensure that all employees comply with the relevant laws, rules and regulations  
15 associated with their employment, including laws prohibiting insider trading  
16 (which are discussed in further detail in Section 3 below). While we do not expect  
17 you to memorize every detail of these laws, rules and regulations, we want you to  
18 be able to determine when to seek advice from others. If you do have a question  
19 in the area of legal compliance, it is important that you not hesitate to seek answers  
20 from your supervisor or the Chief Compliance Officer, or in the absence of an  
21 appointed Chief Compliance Officer, the General Counsel (as further described in  
22 Section 23). In the absence of an appointed Chief Compliance Officer, all  
23 references to Chief Compliance Officer in this Code shall mean General Counsel.

24 Disregard of the law will not be tolerated. Violation of domestic or foreign laws,  
25 rules and regulations may subject an individual, as well as the Company, to civil  
26 and/or criminal penalties. You should be aware that conduct and records, including  
27 emails and chat transcripts, are subject to internal and external audits and to  
28 discovery by third parties in the event of a government investigation or civil  
litigation. You must fully cooperate with any such audits and investigations,  
including by providing truthful, accurate and complete information and complying  
with any applicable instructions provided by the Legal department.

56. In a section titled “Insider Trading,” the Code of Conduct states:

Employees who have access to confidential (or “inside”) information obtained  
through their position at the Company are not permitted to use or share that  
information for stock trading purposes or for any other purpose except to conduct  
our business. All non-public information about the Company or about companies  
with which we do business is considered confidential information. To use material  
non-public information in connection with buying or selling securities, including  
“tipping” others who might make an investment decision on the basis of this

1 information, is not only unethical, it is illegal. Employees must exercise the utmost  
2 care when handling material inside information. Please refer to the Company's  
Insider Trading Policy for more detailed information.

3 57. In a section titled "Protection and Proper Use of Company Assets," the Code of  
4 Conduct states the following, in relevant part:

5 All employees are expected to protect our assets and ensure their efficient use.  
6 Theft, carelessness, and waste have a direct impact on our profitability. Our  
7 property, such as office supplies, computer equipment, and buildings, are expected  
8 to be used only for legitimate business purposes, although incidental personal use  
9 may be permitted, provided that the use complies with Company policy. You may  
10 not, however, use our corporate name, any brand name or trademark owned or  
11 associated with the Company or any letterhead for any personal purpose. You may  
12 not, while acting on behalf of the Company or while using our computing or  
13 communications equipment or facilities, either: • access the internal computer  
14 system or other resource of another entity without express written authorization  
from the entity responsible for operating that resource; or • violate the intellectual  
property or privacy rights of others, or commit any unlawful or illegal act,  
including harassment, libel, fraud, sending of unsolicited bulk email (also known  
as "spam") or material of objectionable content in violation of applicable law,  
trafficking in contraband of any kind or any kind of espionage.

15 58. In a section titled "Conflicts of Interest," the Code of Conduct states the following,  
16 in relevant part:

17 We respect the rights of our employees to manage their personal affairs and  
18 investments and do not wish to impinge on their personal lives. At the same time,  
19 employees should avoid conflicts of interest that occur when their personal  
20 interests may interfere in any way with the performance of their duties or the best  
21 interests of the Company. A conflicting personal interest could result from an  
22 expectation of personal gain now or in the future or from a need to satisfy a prior  
23 or concurrent personal obligation. We expect our employees to be free from  
24 influences that conflict with the best interests of the Company or might deprive  
the Company their undivided loyalty in business dealings. Even the appearance of  
a conflict of interest where none actually exists can be damaging and should be  
avoided. Whether or not a conflict of interest exists or will exist can be unclear.  
Conflicts of interest are prohibited unless specifically authorized as described  
below.

25 If you have any questions about a potential conflict or if you become aware of an  
26 actual or potential conflict, and you are not an officer or director of the Company,  
27 you should discuss the matter with your supervisor or the Chief Compliance  
Officer. Supervisors may not authorize conflict of interest matters or make

1 determinations as to whether a problematic conflict of interest exists without first  
2 seeking the approval of the Chief Compliance Officer and providing the Chief  
3 Compliance Officer with a written description of the activity. If the supervisor is  
4 involved in the potential or actual conflict, you should discuss the matter directly  
5 with the Chief Compliance Officer. Officers and directors may seek  
6 authorizations and determinations from the Company's Nominating and  
7 Corporate Governance Committee.

8 59. With respect to "Reporting Possible Violations," the Code of Conduct states the  
9 following, in relevant part:  
10

11 If you encounter a situation or are considering a course of action and its  
12 appropriateness is unclear, discuss the matter promptly with your supervisor or the  
13 Chief Compliance Officer; even the appearance of impropriety can be very  
14 damaging and should be avoided.

15 If you are aware of a suspected or actual violation of laws, regulations, the Code  
16 or any other Company policy, you have a responsibility to report it. You are  
17 expected to promptly provide a compliance resource with a specific description of  
18 the violation that you believe has occurred, including any information you have  
19 about the persons involved and the time of the violation. Further, the Company  
20 encourages and expects each of us to report when we feel we are being pressured  
21 to compromise standards that may lead to a potential violation. Please report these  
22 matters directly to your supervisor or the Chief Compliance Officer.

23 Whether you choose to speak with your supervisor or the Chief Compliance  
24 Officer, you should do so without fear of any form of retaliation. The Company  
25 does not tolerate retaliation in any form against anyone who in good faith reports  
26 suspected violations or unethical behavior or who participates in an investigation  
27 regarding suspected violations or unethical behavior. Making a report in "good  
28 faith" means that you have provided all the information you have and that you  
reasonably believe there has been a possible violation of applicable law,  
regulation, rule or standard, this Code or any other Company policy, even if your  
report turns out to be unsubstantiated. If you feel that you have been retaliated  
against in any manner whatsoever, please notify Legal or People Operations  
immediately. Those who engage in retaliation will be subject to disciplinary action  
up to and including termination.

29 If for any reason you do not wish to discuss suspected violations or unethical  
30 behavior directly with the Company, please contact the Company's Toll-Free  
31 Hotline (the "Hotline"). Calls may be made for any reason at any time, around the  
32 clock. In order to provide additional assurance of anonymity, all Hotline calls are  
33 taken by a trained third-party vendor. The toll free number to call in North America  
34 is 877-306- 7946. If you are outside North America, or if you prefer to use the

internet, you may voice your concerns by filling out the web form located at <https://www.whistleblowerservices.com/OM>.

Supervisors must promptly report any complaints or observations of Code violations to the Chief Compliance Officer. If you believe your supervisor has not taken appropriate action, you should contact the Chief Compliance Officer directly. The Chief Compliance Officer will investigate all reported possible Code violations promptly and with the highest degree of confidentiality that is possible under the specific circumstances. Neither you nor your supervisor may conduct any preliminary investigation, unless authorized to do so by the Chief Compliance Officer. Your cooperation in the investigation will be expected. As needed, the Chief Compliance Officer will consult with legal counsel, the People Operations department and/or Audit Committee of the Board of Directors. It is our policy to employ a fair process by which to determine violations of the Code.

With respect to any complaints or observations of violations that may involve accounting, internal accounting controls and auditing concerns, under the Company's Whistleblower Policy, the Chief Compliance Officer shall promptly inform the Audit Committee, and the Audit Committee shall be responsible for supervising and overseeing the inquiry and any investigation that is undertaken. If a potential violation is reported via the confidential hotline or email address as provided under the Whistleblower Policy, the Audit Committee will be notified automatically and directly.

If any investigation indicates that a violation of the Code has probably occurred, we will take such action as we believe to be appropriate under the circumstances. If we determine that an employee is responsible for a Code violation, he or she will be subject to disciplinary action up to, and including, termination of employment and, in appropriate cases, civil action or referral for criminal prosecution.

Appropriate action may also be taken to deter any future Code violations.

### **OUTSET'S AUDIT COMMITTEE CHARTER**

60. According to Outset's Audit Committee Charter, the purpose of the Audit Committee is to assist the Board in its oversight of:

(i) the Company's accounting and financial reporting processes and the audit of the Company's financial statements, (ii) the Company's compliance with legal and regulatory requirements, (iii) the qualifications and independence of the Company's external auditor (the "Independent Auditor"), and (iv) the performance of the Company's internal auditing function ("Internal Audit") and the Independent Auditor. The Committee shall also prepare the report of the Committee required to be included in the Company's annual report or proxy statement relating to the election of directors. The Board recognizes that while the

1 Committee has been given certain duties and responsibilities pursuant to this  
2 Charter, the Committee is not responsible for guaranteeing the accuracy of the  
3 Company's financial statements or the quality of the Company's accounting and  
financial reporting processes. The fundamental responsibility for the Company's  
financial statements and disclosures rests with management.

4 61. In a section titled "Duties and Responsibilities," the Audit Committee Charter  
5 states that the Audit Committee shall:

6 1. Be directly responsible for the appointment, compensation, retention, oversight  
7 of the work of, and termination of the Independent Auditor and any other  
8 independent registered public accounting firm engaged for the purpose of  
9 preparing or issuing an audit report or performing other audit, review or attest  
10 services for the Company. The Committee shall also be responsible for the  
11 resolution of disagreements between management and the Independent Auditor  
and any such other firm regarding accounting and financial reporting. The  
Independent Auditor and any such other firm shall report directly to the  
Committee.

12 2. Meet to review and discuss the annual audited financial statements and quarterly  
13 financial statements with management and the Independent Auditor, including the  
14 disclosures under the caption "Management's Discussion and Analysis of  
15 Financial Condition and Results of Operations." The Committee shall make  
a recommendation to the Board as to whether the annual audited financial  
statements should be included in the Company's Annual Report on Form 10-K.

16 3. Discuss earnings press releases, as well as financial information and earnings  
17 guidance provided to analysts and ratings agencies.

\* \* \*

18 7. Obtain and review annually, prior to the completion of the Independent  
19 Auditor's annual audit of the Company's year-end financial statements (the  
20 "Annual Audit"), a report from the Independent Auditor, describing (i) all critical  
21 accounting policies and practices to be reflected in the Annual Audit, (ii) all  
22 alternative treatments of financial information within generally accepted  
23 accounting principles ("GAAP") for policies and procedures related to material  
24 items that have been discussed with management, ramifications of the use of such  
25 alternative disclosures and treatments, and the treatment preferred by the  
Independent Auditor, and (iii) other material written communications between the  
Independent Auditor and management, such as any management letter or schedule  
of unadjusted differences. Review any reports on such topics or similar topics  
prepared by management. Discuss with the Independent Auditor any material  
issues raised in such reports.

26 8. Review and evaluate the lead audit partner of the Independent Auditor (taking  
27 into account the opinions of management and Internal Audit (if applicable)) and  
28

1 assure the regular rotation of the lead audit partner, the concurring partner and  
2 other audit partners engaged in the Annual Audit, to the extent required by law.

3 9. Review the Company's financial reporting processes and internal controls,  
4 based on consultation with the Independent Auditor and Internal Audit (if  
5 applicable). Such review shall include a consideration of major issues regarding  
6 accounting principles and financial statement presentations, including any  
7 significant changes in the Company's selection or application of accounting  
8 principles, and major issues as to the adequacy of the Company's internal controls  
9 and any special audit steps adopted in light of identified deficiencies. Review any  
10 analyses prepared by management and/or the Independent Auditor setting forth  
11 significant financial reporting issues and judgments made in connection with the  
12 preparation of the financial statements, including analyses of the effects of  
13 alternative GAAP methods on the financial statements.

14 \* \* \*

15 27. Prepare the report of the Committee required to be included in the Company's  
16 annual report or proxy statement.

17 \* \* \*

18 30. Conduct an annual performance evaluation of the Committee and its members,  
19 including a review of adherence to this Charter.

20 31. Review the adequacy of this Charter annually and recommend any proposed  
21 changes to the Board for approval.

22 \* \* \*

23 33. Perform such other duties and responsibilities, consistent with this Charter, the  
24 Company's bylaws, governing law, the rules and regulations of Nasdaq, the  
25 federal securities laws and such other requirements applicable to the Company,  
26 delegated to the Committee by the Board.

27 62. In a subsection titled "Form 10-Q Review," the Audit Committee Charter states  
28 that the Audit Committee "must review and discuss the quarterly financial statements with  
management and the independent auditor, including the Company's disclosures under  
'Management's Discussion and Analysis of Financial Condition and Results of Operations' for  
inclusion in the Company's Quarterly Reports on Form 10-Q."

63. In a subsection titled "Risk Assessment and Management," the Audit Committee  
Charter states:

The Committee must oversee enterprise risk management, including the  
management of financial risks; review and discuss the Company's guidelines and  
policies with respect to risk assessment and risk management; and discuss with

1 management the steps management has taken to monitor and control these  
 2 exposures. The Committee must discuss with management and the independent  
 3 auditors correspondence with regulators or governmental agencies that raise  
 4 material issues regarding the Company's financial statements or accounting  
 5 policies.

6 64. With respect to internal controls over financial reporting, the Audit Committee  
 7 Charter states:

8 The Committee must review and discuss with management, the internal auditor  
 9 (or other personnel responsible for the internal audit function), once established,  
 10 and the independent auditor, the adequacy and effectiveness of the Company's  
 11 internal control over financial reporting ("ICFR"), the adequacy of the Company's  
 12 disclosures about changes in ICFR and any steps management has taken to address  
 13 material deficiencies in ICFR. The Committee must review and discuss with  
 14 management and the independent auditor management's report on ICFR and the  
 15 independent auditor's attestation report on the Company's ICFR for purposes of  
 16 the Company's Annual Report on Form 10-K, to the extent such reports are  
 17 required.

## 18 **SUBSTANTIVE ALLEGATIONS**

### 19 **Section 510(k)**

20 65. Section 510(k) of the Federal Food, Drug, and Cosmetic Act, 21 C.F.R. §  
 21 807.81(a), provides a marketing clearance process for device manufacturers seeking to market a  
 22 device intended for human use in the United States. Section 510(k) requires a premarket  
 23 submission to the FDA that demonstrates a manufacturer's device is as safe and effective as a  
 24 device that is already legally marketed. Until the submitter receives an order from the FDA  
 25 declaring a device substantially equivalent to a predicate device, the submitter cannot market the  
 26 device.

27 66. A "legally marketed device" may include a device: (i) legally marketed prior to  
 28 May 28, 1976 (a "pre-amendments device"); (ii) previously approved via Premarket Approval  
 ("PMA") and later reclassified; (iii) found substantially equivalent by the FDA through the  
 Section 510(k) process; or (iv) exempt from Section 510(k).

67. To establish substantial equivalence to a legally marketed device under Section  
 510(k), the device must: (1) have the same intended use and technological characteristics of the

1 predicate device; **or** (2) have the same intended use and different technological characters that do  
2 not raise different questions of safety and effectiveness and the information submitted to FDA  
3 must demonstrate that the device is as safe and effective as the legally marketed device.

4 68. Any significant modifications that impact the safety and/or efficacy of a device  
5 previously granted 510(k) clearance may require the submission of additional 510(k) applications  
6 and subsequent FDA clearances.

7 69. Educational, promotional, and training activities must comply with FDA  
8 regulations and other applicable laws. Relevantly, device manufacturers are prohibited from  
9 promoting a medical device for a use that has not been cleared or approved by the FDA.

10 70. If the FDA determines that educational, promotional, and training activities  
11 constitute promotion of an “off-label” use, meaning the use of a device outside of its cleared or  
12 approved indications, it may request that a company modify its training or promotional materials  
13 or subject the company to regulatory or enforcement actions, including the issuance of warning  
14 letters, untitled letters, fines, penalties, injunctions or seizures. Additionally, other federal, state  
15 or foreign enforcement authorities might also take action, which could result in significant fines  
16 or penalties under other statutory authorities, such as laws prohibiting false claims for  
17 reimbursement.

18 **Outset and Its Tablo and TabloCart Products**

19 71. Outset is a medical technology company that focuses on kidney dialysis systems.  
20 The Company’s primary products are Tablo and TabloCart, innovative devices used in kidney  
21 dialysis treatment.

22 72. Tablo is a hemodialysis machine, which the Company markets as a single  
23 enterprise dialysis solution that allows providers to standardize hemodialysis to a single  
24 technology platform requiring only an electrical outlet and tap water to operate.

25 73. In September 2014, Tablo received clearance under Section 510(k) for use in  
26 patients with acute and/or chronic renal failure, with or without ultrafiltration, in both acute and  
27 chronic care facilities.

1           74. On March 31, 2020, Tablo was cleared by the FDA under Section 510(k) for  
2 patient use in the home.

3           75. In October 2022, Outset introduced the TabloCart, an accessory designed to  
4 purportedly enhance maneuverability and optimize water pre-filtration in environments with  
5 compromised water quality.

6           **Outset's Initial Public Offering**

7           76. Outset initiated its initial public offering ("IPO") on September 15, 2020. In  
8 connection with the IPO, the Company submitted a registration statement on a Form S-1 with the  
9 SEC on August 21, 2020. Subsequently, the Company filed amendments to the registration  
10 statement with the SEC on September 9, 2020, and September 14, 2020 (as amended, the "IPO  
11 Registration Statement"). Additionally, on September 16, 2020, the Company filed a prospectus  
12 in connection with the IPO on a Form 424B4 with the SEC (the "IPO Prospectus," and together  
13 with the IPO Registration Statement, the "IPO Documents").

14           77. During the IPO, Outset issued 10,293,777 shares of its common stock at a price of  
15 \$27.00 per share. As a result of the IPO, the Company received approximately \$277.9 million in  
16 gross proceeds and the Company's stock began trading on the NASDAQ under the ticker symbol  
17 "OM."

18           78. The IPO Documents were signed by Defendants Trigg, Chambers, Grossman,  
19 Carella, Hackett, Hinrichs, and Osman.

20           **Defendants' Materially False and Misleading Statements**

21           79. The Relevant Period began September 15, 2020, the day that Outset launched its  
22 IPO.

23           80. Within the IPO Documents, Outset touted Tablo's portability and diverse use,  
24 stating that Tablo was a "dialysis clinic on wheels" and, in relevant part, that:

25           Our technology is designed to elevate the dialysis experience for patients, and help  
26 providers overcome traditional care delivery challenges. Requiring only an  
27 electrical outlet and tap water to operate. Tablo frees patients and providers from  
28 the burdensome infrastructure required to operate traditional dialysis machines.

1 The integration of water purification and on-demand dialysate production enables  
2 Tablo to serve as a dialysis clinic on wheels and allows providers to standardize  
to a single technology platform from the hospital to the home.

3 81. The IPO Documents also stated that “Tablo is currently cleared by the United  
4 States Food and Drug Administration (FDA) for use in the hospital, clinic or home setting” and  
5 that Outset’s “policy is to refrain from statements that could be considered off-label promotion of  
6 Tablo.” Further, the IPO Documents stated that “Tablo is the first and only fully integrated  
7 hemodialysis system that can be used to deliver treatment across all care settings from the ICU to  
8 home.”

9 82. On November 11, 2020, Outset issued a press release announcing its financial  
10 results for the third quarter of 2020, which stated that the Company had “[r]ecorded net revenue  
11 of \$13.8 million in the third quarter of 2020, a 423% increase compared to \$2.6 million in the  
12 third quarter of 2019.”

13 83. In the same press release, Defendant Trigg was quoted as stating: “[o]ur  
14 commercial momentum continued to accelerate in the third quarter as we signed new contracts  
15 with some of the largest national and regional health systems in the country.”

16 84. On November 12, 2020, Outset filed its quarterly report for the period ended  
17 September 30, 2020 on a Form 10-Q with the SEC (the “3Q20 10-Q”). The 3Q20 10-Q was signed  
18 by Defendants Trigg and Chambers and accompanied by certifications pursuant to Rules 13a-  
19 14(a) and 15d-15(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-  
20 Oxley Act of 2002 (the “SOX Certifications”), wherein Defendants Trigg and Jacobson attested  
to the accuracy of the 3Q20 10-Q.

21 85. The 3Q20 10-Q confirmed the previously disclosed financial results and further  
22 stated:

23 Our technology is designed to elevate the dialysis experience for patients, and  
24 help providers overcome traditional care delivery challenges, requiring only an  
25 electrical outlet and tap water to operate. Tablo frees patients and  
26 providers from the burdensome infrastructure required to operate traditional  
dialysis machines. The integration of water purification and on-demand  
27 dialysate production enables Tablo to serve as a dialysis clinic on wheels and

1 allows providers to standardize to a single technology platform from the hospital  
2 to the home.

3 86. Like the IPO Documents, the 3Q20 10-Q stated that “Tablo is currently cleared by  
4 the United States Food and Drug Administration (FDA) for use in the hospital, clinic or home  
5 setting” and that Outset’s “policy is to refrain from statements that could be considered off-label  
6 promotion of Tablo.”

7 87. On March 9, 2021, Outset issued a press release announcing its financial results  
8 for the fourth quarter and full year of 2020, wherein the Company reported that it had “[r]ecorded  
9 net revenue of \$17.2 million in the fourth quarter and \$49.9 million for the full year of 2020,  
10 representing 143% and 231% increases respectively, over the corresponding periods of 2019.”

11 88. In the same press release, Defendant Trigg was quoted as stating “[i]n the fourth  
12 quarter our team continued to outperform while building a solid foundation for growth through  
13 2021 and beyond.”

14 89. On March 22, 2021, the Company filed its 2020 annual report on a Form 10-K  
15 with the SEC (the “2020 10-K”). The 2020 10-K was signed by Defendants Trigg, Chambers,  
16 Grossman, Drexler, Hackett, Hinrichs, and Osman and accompanied by SOX Certifications made  
17 by Defendants Trigg and Chambers, wherein they attested to the accuracy of the 2020 10-K.

18 90. The 2020 10-K stated, in relevant part:

19 Our technology is designed to elevate the dialysis experience for patients, and help  
20 providers overcome traditional care delivery challenges. Requiring only an  
21 electrical outlet and tap water to operate. Tablo frees patients and providers from  
22 the burdensome infrastructure required to operate traditional dialysis machines.  
23 The integration of water purification and on-demand dialysate production enables  
24 Tablo to serve as a dialysis clinic on wheels and allows providers to standardize  
25 to a single technology platform from the hospital to the home.

26 91. The 2020 10-K also stated that “Tablo is currently cleared by the United States  
27 Food and Drug Administration (FDA) for use in the hospital, clinic or home setting” and that  
28 Outset’s “policy is to refrain from statements that could be considered off-label promotion of  
29 Tablo.” The 2020 10-K further stated that “Tablo is the first and only fully integrated

1 hemodialysis system that can be used to deliver treatment across all care settings from the ICU to  
2 home.”

3 92. On April 21, 2021, Outset filed a proxy statement on a Schedule 14A with the SEC  
4 (the “2021 Proxy Statement”). With respect to risk oversight, the 2021 Proxy Statement stated:

5 One of the key functions of our board of directors is informed oversight of our risk  
6 management process. Our board of directors’ role in risk oversight is consistent  
7 with our leadership structure, with management having day-to-day responsibility  
8 for assessing and managing our risk exposure and our board of directors actively  
9 overseeing management of our risks – both at the board of directors and committee  
10 level. The risk oversight process includes receiving regular reports from  
11 committees and management to enable our board of directors to understand our  
12 risk identification, risk management and risk mitigation strategies with respect to  
13 areas of potential material risk, including operations, information technology  
14 (including cybersecurity), finance, legal, regulatory, strategic and reputational  
15 risk. Our board of directors focuses on the overall risks affecting us, and each of  
16 its standing committees has been delegated responsibility for oversight of specific  
17 risks that fall within its areas of responsibility. For example:

- 18 • Our Audit Committee is responsible for overseeing our major financial,  
19 legal and regulatory risk exposures, which spans a variety of areas  
20 including litigation, regulatory compliance, financial reporting,  
21 insurance and cybersecurity. Our audit committee also oversees the steps  
22 management has taken to monitor and control such exposures, including  
23 guidelines and policies for assessing and managing risk and related  
24 compliance efforts. . . .

25 While each committee is responsible for evaluating certain risks and overseeing  
26 the management of such risks, the full board of directors is regularly informed  
27 through committee reports about such risks.

28 93. On May 5, 2021, Outset issued a press release announcing its financial results for  
the first quarter of 2021, wherein the Company reported that it had “[r]ecorded net revenue of  
\$22.9 million in the first quarter of 2021, a 219% increase compared to \$7.2 million in the first  
quarter of 2020.”

94. In the same press release, Defendant Trigg was quoted as stating:

Our first quarter was marked by strong revenue performance, continued  
operational execution, and substantial progress across our strategic initiatives[.]  
Demand for Tablo is both increasing and extending beyond the acute and subacute

1 care settings, with a growing number of customers preparing for home care  
2 programs. With strong interest in Tablo, a robust backlog and clear visibility on  
the timing of console placements, we are confident in our positioning for  
consistent strong performance in 2021 and beyond.

3 95. On May 5, 2021, the Company filed its quarterly report for the period ended March  
4 31, 2021 on a Form 10-Q with the SEC (the “1Q21 10-Q”). The 1Q21 10-Q was signed by  
5 Defendants Trigg and Chambers and was accompanied by SOX Certifications made by  
6 Defendants Trigg and Chambers, wherein they attested to the accuracy of the 1Q21 10-Q.

7 96. In addition to confirming Outset’s financial results for the first quarter of 2021,  
8 the 1Q21 10-Q again stated that Tablo serves as “a dialysis clinic on wheels” and that:

9 Our technology is designed to elevate the dialysis experience for patients, and  
10 help providers overcome traditional care delivery challenges. Requiring only an  
electrical outlet and tap water to operate, Tablo frees patients and  
11 providers from the burdensome infrastructure required to operate traditional  
dialysis machines. The integration of water purification and on-demand  
12 dialysate production enables Tablo to serve as a dialysis clinic on wheels and  
allows providers to standardize to a single technology platform from the hospital  
13 to the home.

14 97. The 1Q21 10-Q further stated that “Tablo is cleared by the U.S. Food and Drug  
15 Administration (FDA) for use in the hospital, clinic or home setting.”

16 98. On August 5, 2021, Outset issued a press release announcing its financial results  
17 for the second quarter of 2021, wherein the Company reported that it had “[r]ecorded net revenue  
18 of \$25.2 million in the second quarter of 2021, a 115% increase compared to \$11.7 million in the  
19 second quarter of 2020.”

20 99. In the same press release, Defendant Trigg was quoted as stating:

21 In the first half of 2021, we delivered best-in-class revenue growth and steady  
gross margin improvement driven by a team that is dedicated to, and united  
22 around, transforming the dialysis experience for patients and providers[.] With  
new home console bookings up substantially in the second quarter, and both  
23 current and new customers purchasing Tablo for acute use, our integrated  
commercial strategy is working as expected. We remain confident in our ability  
24 to execute on each of our key strategic initiatives for 2021 and in our long-term  
growth prospects.  
25  
26  
27  
28

100. On August 6, 2021, the Company filed a quarterly report for the period ended June 30, 2021 on a Form 10-Q with the SEC (the “2Q21 10-Q”). The 2Q21 10-Q was signed by Defendants Trigg and Ahmed and was accompanied by SOX Certifications made by Defendants Trigg and Ahmed, wherein they attested to the accuracy of the 2Q21 10-Q.

101. The 2Q21 10-Q confirmed Outset’s previously announced financial results for the quarter and contained the same materially false and misleading statements as the 1Q21 10-Q.

102. On November 3, 2021, Outset issued a press release announcing its financial results for the third quarter of 2021, wherein the Company reported that it had “[r]ecorded net revenue of \$26.3 million in the third quarter of 2021, a 91.3% increase compared to \$13.8 million in the third quarter of 2020.”

103. In the same press release, Defendant Trigg is quoted as stating that, “[o]ur strong third quarter performance further reinforces our confidence in our business and in our expectations for growth.”

104. On November 4, 2021, Outset filed its quarterly report for the period ended September 30, 2021 on a Form 10-Q with the SEC (the “3Q21 10-Q”). The 3Q21 10-Q was signed by Defendants Trigg and Ahmed and was accompanied by SOX Certifications made by Defendants Trigg and Ahmed, wherein they attested to the accuracy of the 3Q21 10-Q.

105. In addition to confirming Outset’s previously disclosed financial results, the 3Q21 10-Q stated, in relevant part:

Our technology is designed to elevate the dialysis experience for patients, and help providers overcome traditional care delivery challenges. Requiring only an electrical outlet and tap water to operate, the Tablo® Hemodialysis System frees patients and providers from the burdensome infrastructure required to operate traditional dialysis machines. The integration of water purification and on-demand dialysate production enables Tablo to serve as a dialysis clinic on wheels and allows providers to standardize to a single technology platform from the hospital to the home.

106. The 3Q21 10-Q further stated that “Tablo is cleared by the U.S. Food and Drug Administration (“FDA”) for use in the hospital, clinic or home setting.”

1           107. On November 7, 2021, Outset published its “ESG Report” on its website, which  
2 stated, in relevant part:

3           Outset had adopted a promotional material procedure to define acceptable and  
4 unacceptable advertising, sales support, training, and other promotional practices  
5 for Outset medical devices in the United States. Included in this procedure is  
6 Outset’s policy that all claims with respect to Outset products must be consistent  
7 with approved labeling, with the data submitted to the FDA to obtain 510(k)  
8 clearance and/or substantiated with appropriate evidence (i.e., instructions-for-  
9 use, verification and validation testing, clinical study report, or any other report  
10 requiring a similar rigorous process of review and approval). In addition, without  
11 exception, promotional material may be neither false nor misleading (either in  
terms of a specific product claim or the overall net impression conveyed by the  
promotional material) and must comply with all specific conditions of approval  
for the product being promoted. Furthermore, promotional materials for a cleared  
or approved product may not promote, discuss, or refer to uncleared, unapproved,  
or off-label use.

12           108. On February 16, 2022, Outset issued a press release announcing its financial  
13 results for the fourth quarter and full year of 2021, wherein the Company stated that it had  
14 “[r]ecorded net revenue of \$28.2 million in the fourth quarter of 2021, a 63.2% increase compared  
15 to \$17.2 million in the fourth quarter of 2020, and \$102.6 million for the full year of 2021,  
16 representing an increase of 105.5% compared to \$49.9 million for 2020.”

17           109. In the same press release, Defendant Trigg was quoted as stating:

18           Our entire team contributed to an exceptional 2021, driving record revenue  
19 growth, meaningful progress toward our long-term gross margin goal and  
20 excellent visibility into 2022[.] Our established relationships with 7 of the 8 largest  
21 national health systems and one-third of the largest 100 regional health systems  
puts us in a strong position for growth this year in both the acute and home settings.

22           110. On February 23, 2022, Outset filed its annual report for 2021 on a Form 10-K  
23 with the SEC (the “2021 10-K”). The 2021 10-K was signed by Defendants Trigg, Ahmed,  
24 Grossman, Drexler, Hackett, Hinrichs, Saia, and Szyman. The 2021 10-K was also accompanied  
25 by SOX Certifications made by Defendants Trigg and Ahmed, wherein they attested to the  
26 accuracy of the 2021 10-K.

111. The 2021 10-K contained the same materially false and misleading statements as the 2020 10-K.

112. On April 14, 2022, Outset filed a proxy statement on a Schedule 14A with the SEC (the “2022 Proxy Statement”). With respect to risk oversight, the 2022 Proxy Statement stated:

One of the key functions of our Board is informed oversight of our risk management process. Our Board’s role in risk oversight is consistent with our leadership structure, with management having day-to-day responsibility for assessing and managing our risk exposure and our Board actively overseeing management of our risks – both at the Board and committee level. The risk oversight process includes receiving regular reports from committees and management to enable our Board to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, information technology (including cybersecurity and data privacy), finance, legal, regulatory, strategic and reputational risk. Our Board focuses on the overall risks affecting us, and each of its standing committees has been delegated responsibility for oversight of specific risks that fall within its areas of responsibility. For example:

- Our Audit Committee is responsible for overseeing our major financial, legal and regulatory risk exposures, which spans a variety of areas including litigation, regulatory compliance, financial reporting and insurance, as well as data privacy, cybersecurity and other information technology risks. Our Audit Committee also oversees the steps management has taken to monitor and control such exposures, including guidelines and policies for assessing and managing risk and related compliance efforts. . . .

While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the full Board is regularly informed through committee reports about such risks.

113. On May 4, 2022, Outset issued a press release announcing its financial results for the first quarter of 2022, wherein the Company reported that it had “[r]ecorded net revenue of \$30.6 million in the first quarter of 2022, a 33.3% increase compared to \$22.9 million in the first quarter of 2021 and an 8.5% increase compared to \$28.2 million in the fourth quarter of 2021.”

114. In the same press release, Defendant Trigg was quoted as stating:

The first quarter of 2022 was marked by strong revenue growth and gross margin expansion, which resulted from the momentum we see among both acute care customers and providers expanding access to Tablo at Home[.] As

1 interest for Tablo accelerates across all market segments, we continued to  
2 expand gross margins, invest in innovation, and deliver consistent and  
3 predictable financial and operational results, increasing our confidence for  
4 sustained strong performance through 2022 and beyond.

5 115. On May 5, 2022, Outset filed its quarterly report for the period ended March 31,  
6 2022 on a Form 10-Q with the SEC (the “1Q22 10-Q”). The 1Q22 10-Q was signed by Defendants  
7 Trigg and Ahmed and was accompanied by SOX Certifications made by Defendants Trigg and  
8 Ahmed, wherein they attested to the accuracy of the 1Q22 10-Q.

9 116. In addition to confirming Outset’s financial results for the first quarter of 2022,  
10 the 1Q22 10-Q stated, in relevant part:

11 Our technology is designed to elevate the dialysis experience for patients and  
12 help providers overcome traditional care delivery challenges. Requiring only an  
13 electrical outlet and tap water to operate, the Tablo® Hemodialysis System frees  
14 patients and providers from the burdensome infrastructure required to operate  
15 traditional dialysis machines. The integration of water purification and on-  
16 demand dialysate production in a single 35-inch compact console enables Tablo  
17 to serve as a dialysis clinic on wheels.

18 117. The 1Q22 10-Q also stated that “Tablo is cleared by the FDA for use in the  
19 hospital, clinic, or home setting.”

20 118. On August 1, 2022, Outset issued a press release announcing its financial results  
21 for the second quarter of 2022, wherein the Company reported that “[r]evenue for the second  
22 quarter totaled \$25.1 million, in line with guidance provided on June 13, 2022.”

23 119. In the same press release, Defendant Trigg was quoted as stating, in relevant part,  
24 that “[a]s we look to the second half of the year, we see no change in underlying demand for  
25 Tablo. However, we have reflected in our guidance the staffing and inflationary pressures our  
26 provider customers are facing, as well as the work we need to do to regain commercial momentum  
27 following release of the Tablo ship hold.”

28 120. In the same press release, Outset also “announced clearance by the Food and Drug  
Administration of its previously disclosed 510(k) submission and resumption of Tablo®  
Hemodialysis System shipments for home use.”

1 121. On August 2, 2022, the Company filed its quarterly report for the period ended  
2 June 30, 2022, on a Form 10-Q with the SEC (the “2Q22 10-Q”). The 2Q22 10-Q was signed by  
3 Defendants Trigg and Ahmed and was accompanied by SOX Certifications made by Defendants  
4 Trigg and Ahmed, wherein they attested to the accuracy of the 2Q22 10-Q.

5 122. In addition to confirming the Company’s previously disclosed financial results,  
6 the 2Q22 10-Q discussed the shipment hold on Tablo for the first time in its SEC filings. However,  
7 the Company assured investors that Tablo was cleared for in home use and that FDA approval  
8 had been secured, and that sales and marketing were on track, stating, in relevant part:

9 Tablo is cleared by the FDA for use in the hospital, clinic, or home setting. In  
10 May 2022, we implemented a shipment hold on the distribution and marketing  
11 of Tablo for use in the home environment pending the FDA’s review and  
12 clearance of a 510(k) application we submitted for changes made since the  
13 device’s original March 2020 clearance. During the hold, we continued to  
14 market and ship Tablo for use by healthcare professionals in chronic and acute  
15 care settings. In addition, the devices that were already distributed to home users  
16 at the time the hold was implemented were not removed and current users were  
17 able to continue working with their healthcare providers on appropriate  
18 treatment. In late July 2022, the FDA cleared our 510(k) application of Tablo  
19 for patient use in the home and we have resumed marketing and shipping Tablo  
20 for home use. Driving adoption of Tablo in the acute care setting has been our  
21 primary focus to date. We have invested in growing our economic and clinical  
22 evidence, built a veteran sales and clinical support team with significant  
23 expertise, and implemented a comprehensive training and customer experience  
24 program. Our experience in the acute care market has demonstrated Tablo’s  
25 clinical flexibility and operational versatility, while also delivering meaningful  
26 cost savings to the providers. We plan to continue leveraging our commercial  
27 infrastructure to broaden our installed base in the acute care market as well as  
28 driving utilization and fleet expansion with our existing customers.

123. On November 8, 2022, Outset issued a press release announcing its financial  
results for the third quarter of 2022, wherein the Company reported that it had “[r]ecorded net  
revenue of \$27.8 million in the third quarter of 2022, a 5.5% increase compared to \$26.3 million  
in the third quarter of 2021 and a 10.8% increase compared to \$25.1 million in the second quarter  
of 2022” and “achieved gross margin for the third quarter of 2022 of 15.6%, compared to 11.2%  
in the third quarter of 2021 and 15.1% in the second quarter of 2022” and that the Company

1 “[r]esumed shipments to new home patients, and grew the Tablo home patient base beyond initial  
2 expectations for the third quarter” and that the Company was “[a]warded five-year contract by  
3 the Department of Veterans Affairs, enabling Tablo to be sold into the 1061 VA hospitals across  
4 the U.S. as well as into home settings.”

5 124. In the same press release, Defendant Trigg was quoted as stating:

6 Our third quarter results reflect the value Tablo is delivering in both the acute  
7 and home settings, with console shipments exceeding our initial  
8 expectations[.] We believe our continued expansion in the acute setting and our  
9 strong start to rebuilding the home patient pipeline reflects patient preference  
10 for Tablo and strong demand across end markets.

11 125. On the same day, Outset hosted an earnings call for investors and analysts to  
12 discuss its financial results for the third quarter of 2022, wherein Defendant Trigg introduced a  
13 new product to its lineup called TabloCart, stating, in relevant part:

14 To that end, we are pleased to introduce TabloCart, which is a new accessory  
15 for Tablo. TabloCart provides additional maneuverability around the  
16 hospital and incremental pre-filtration capabilities for sites that suffer from  
17 water quality that is far worse than the national drinking water standards.  
18 TabloCart will be sold separately at an expected margin accretive ASP. We  
19 closed Q3 exceeding our internal projections for TabloCart orders indicating  
20 strong early demand for this innovative accessory.

21 In summary, our strong Q3 was driven by significant expansion in the acute  
22 setting and a home pipeline that is rebuilding ahead of expectations. It is clear  
23 to us that Tablo remains a highly differentiated solution in one of the largest,  
24 most expensive recession proof areas of healthcare. Our performance reflects  
25 the truly incredible Outset team who I would like to thank for their courage,  
26 commitment, and conviction in all they do every day to advance our mission.

27 126. On November 9, 2022, Outset filed its quarterly report for the period ended  
28 September 30, 2022 on a Form 10-Q with the SEC (the “3Q22 10-Q”). The 3Q22 10-Q was signed  
by Defendants Trigg and Ahmed and was accompanied by SOX Certifications made by  
Defendants Trigg and Ahmed, wherein they attested to the accuracy of the 3Q22 10-Q.

127. In addition to confirming Outset’s previously disclosed financial results, the 3Q22  
10-Q stated, in relevant part:

1 In May 2022, we implemented a shipment hold on the distribution and marketing  
2 of Tablo for use in the home environment pending the FDA's review and  
3 clearance of a 510(k) application we submitted for changes made since the  
4 device's original March 2020 clearance. . . .

5 In late July 2022, the FDA cleared our 510(k) application of Tablo for patient  
6 use in the home and we resumed marketing and shipping Tablo for home use.

7 Driving adoption of Tablo in the acute care setting has been our primary focus  
8 to date. We have invested in growing our economic and clinical evidence, built  
9 a veteran sales and clinical support team with significant expertise, and  
10 implemented a comprehensive training and customer experience program.

11 128. On January 9, 2023, Outset issued a press release announcing its preliminary  
12 financial results for the fourth quarter and full year of 2022, as well as its guidance for 2023,  
13 stating, in relevant part:

- 14 • Revenue in the fourth quarter is expected to be approximately \$31.5 million, a  
15 13% increase compared to \$27.8 million in the third quarter of 2022
- 16 • Revenue for 2022 is expected to be approximately \$115 million, a 12%  
17 increase compared to \$102.6 million in 2021
- 18 • Period-end installed base increased 54% year-over-year to approximately  
19 4,000 Tablo® Hemodialysis Systems, including 3,200 with acute- and sub-  
20 acute care providers and a more than doubling of units with home providers to  
21 nearly 800
- 22 • The Company continues to expect its full-year 2022 non-GAAP gross margin  
23 will be in the mid-teens, as previously indicated

24 \* \* \*

25 Outset expects 2023 revenue to be between \$140 million to \$150 million,  
26 growing approximately 22% to 30% over expected revenue for 2022. Non-  
27 GAAP gross margin is expected to expand to approximately 20% for the full  
28 year 2023 and exit the year in the mid-20% range for the fourth quarter of 2023.

129. On February 13, 2023, the Company issued a press release announcing its financial  
results for the fourth quarter and full year of 2022, stating, in relevant part:

- Recorded net revenue of \$32.0 million in the fourth quarter, a 15.3%  
increase compared to \$27.8 million in the third quarter, and a 14.0%  
increase compared to \$28.2 million in the fourth quarter of 2021. Revenue

for the full year was \$115.4 million, an increase of 12.4% compared to \$102.6 million in 2021

- Achieved gross margin for the fourth quarter of 16.5% (17.1% on a non-GAAP basis), compared to 11.8% (12.0% on a non-GAAP basis) in the fourth quarter of 2021. Gross margin for the full year was 15.5% (16.1% on a non-GAAP basis), an increase of more than 800 basis points over 2021

\* \* \*

### Full Year 2023 Financial Guidance

Outset reaffirmed its previously provided guidance for 2023, including revenue of \$140 million to \$150 million, growing approximately 22% to 30% over 2022, and non- GAAP gross margin of approximately 20% for 2023, exiting the year in the mid-20% range for the fourth quarter.

130. On February 13, 2023, Outset filed its annual report for 2022 on a Form 10-K with the SEC (the “2022 10-K”). The 2022 10-K was signed by Defendants Trigg, Ahmed, Grossman, Drexler, Hackett, Hinrichs, Jones, Saia, and Szyman. The 2022 10-K was also accompanied by SOX Certifications made by Defendants Trigg and Ahmed, wherein they attested to the accuracy of the 2022 10-K.

131. The 2022 10-K reaffirmed the Company’s previously disclosed financial results and touted Tablo and TabloCart, as well as the Company’s sales and marketing practices, stating, in relevant part:

Tablo is an FDA-cleared single enterprise solution for hemodialysis, comprised of a compact console with integrated water purification, on-demand dialysate production and advanced software and connectivity capabilities. . . .

We recently introduced TabloCart, a non-medical accessory for the Tablo Hemodialysis System that provides added maneuverability and optional prefiltration storage. . . .

Driving adoption of Tablo in the acute care setting has been our primary focus to date. We have invested in growing our economic and clinical evidence, built a veteran sales and clinical support team with significant expertise, and implemented a comprehensive training and customer experience program. . . .

We sell our solution through our direct sales organization, which covers most major metropolitan markets in the United States. Our sales organization is comprised of our capital sales team, responsible for generating new customer

1 demand for Tablo, and our clinical sales team, responsible for driving utilization  
2 and fleet expansion of Tablo consoles at existing customer sites. . . .

3 We believe the ability to leverage one team to serve both markets will result in  
4 significant productivity and cost optimization as we continue to scale our business.

5 132. Also on February 13, 2023, the Company hosted an earnings call for investors and  
6 analysts to discuss its financial results for the fourth quarter and full year of 2022, during which  
7 Defendant Trigg stated, in part:

8 From a product innovation perspective, last quarter was our first full quarter in  
9 market with TabloCart, a new accessory that provides additional maneuverability  
10 around the hospital and incremental pre-filtration capabilities for sites with water  
11 quality that is far worse than the national drinking water standards. As a reminder,  
12 TabloCart is sold separately at a gross margin accretive ASP [Average Selling  
13 Price]. Since its launch in Q3, we've been pleased with the strong demand  
14 and positive reaction from customers.

15 133. During the same call, Defendant Ahmed highlighted the sales from Tablo and  
16 TabloCart and the impact on the Company's revenue, stating, in relevant part:

17 Our fourth quarter revenue increased approximately 15.3% sequentially and  
18 13.7% year-over-year to \$32 million with a year-over-year change driven  
19 primarily by higher consumables revenue and higher service and other revenue.  
20 This uptick in recurring revenue is one of the benefits of our expanded installed  
21 base and continues to be one of the key drivers of gross margin expansion.

22 Product revenue was up 21.3% from the prior quarter and increased 11.5% year-  
23 over- year to \$26.4 million. Console revenue grew 22.8% from the third  
24 quarter and increased by 1.5% year-over-year to \$18.4 million. We saw console  
25 ASPs increase again year-over-year, driven primarily by the ongoing demand for  
26 Tablo XT and by demand TabloCart, our new accessory launched in the fourth  
27 quarter of 2022. . . .

28 [W]e have absolutely seen ASP increases from the XT attach, which is again  
adding value to our customers instead of monetizing that value, which we like.  
We've also seen TabloCart be a big driver or be a driver rather of ASP sort of lift  
in the quarter here and are really pleased with the performance there.

The one thing, we have also talked a lot about the fact that we haven't had to  
discount very heavily in our past, which we view as again, a testament to Tablo's  
economic value proposition. So pricing, we have no complaints about pricing  
and pricing is favorable, works favorably for us.

134. On April 14, 2023, the Company filed a proxy statement on a Schedule 14A with the SEC (the “2023 Proxy Statement”). With respect to risk oversight, the 2023 Proxy Statement stated:

One of the key functions of our Board is informed oversight of our risk management process. Our Board’s role in risk oversight is consistent with our leadership structure, with management having day-to-day responsibility for assessing and managing our risk exposure and our Board actively overseeing management of our risks – both at the Board and committee level. The risk oversight process includes receiving regular reports from committees and management to enable our Board to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, information technology (including cybersecurity and data privacy), finance, legal, regulatory, strategic and reputational risks. Our Board focuses on the overall risks affecting us, and each of its standing committees has been delegated responsibility for oversight of specific risks that fall within its areas of responsibility. For example:

- Our Audit Committee is responsible for overseeing our major financial, legal and regulatory risk exposures, which spans a variety of areas including litigation, regulatory compliance, financial reporting and insurance, as well as data privacy, cybersecurity and other information technology risks. Our Audit Committee also oversees the steps management has taken to monitor and control such exposures, including guidelines and policies for assessing and managing risk and related compliance efforts. . . .

While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the full Board is regularly informed through committee reports about such risks.

135. On May 3, 2023, Outset issued a press release announcing its financial results for the first quarter of 2023, as well as financial guidance for the remainder of 2023:

#### **First Quarter 2023 Financial Results**

Revenue for the first quarter of 2023 was \$33.5 million, representing an increase of 9.5% compared to \$30.6 million in the first quarter of 2022. Product revenue was \$27.8 million, representing an increase of 8.2% compared to \$25.7 million in the first quarter of 2022. Service and other revenue was \$5.7 million, representing an increase of 16.4% compared to \$4.9 million in the first quarter of 2022.

1 Total gross profit was \$6.4 million, compared to \$4.4 million for the first quarter  
 2 of 2022. Total gross margin was 19.2%, compared to 14.5% in the first quarter of  
 3 2022. On a non-GAAP basis, gross margin improved to 20.3% from 14.8% in the  
 4 first quarter of 2022. . . .

#### 5 **Full Year 2023 Financial Guidance**

6 Outset now projects revenue for 2023 to range from \$144 million to \$150 million,  
 7 which represents approximately 25% to 30% growth over the Company's fiscal  
 8 year 2022 revenue. This updated guidance compares to prior 2023 revenue  
 9 guidance of \$140 million to \$150 million. In addition, the Company expects gross  
 10 margin for the year to be in the low-20% range, up from its prior guidance of  
 11 approximately 20%, and exiting the fourth quarter in the mid-20% range.

12 136. On May 3, 2023, Outset hosted an earnings call for investors and analysts to  
 13 discuss its financial results for the first quarter of 2023, during which Defendant Trigg stated:

14 Another important element of our commercial strategy is to drive utilization across  
 15 the installed base, and we were pleased to see positive trends in treatment volume  
 16 during the quarter, in line with our expectations. We also saw ASPs rise, both on  
 17 consoles and consumables, which serves as strong validation of Tablo's clinical  
 18 and economic value proposition versus our competitors. Our ASPs benefited again  
 19 from better-than-expected uptake of Tablo add-ons, including good early demand  
 20 for our TabloCart new product accessory. . . .

21 From a product innovation standpoint, we are very pleased with demand for  
 22 TabloCart, a new product accessory we introduced in Q3 of last year that provides  
 23 additional maneuverability around the hospital, and incremental water prefiltration  
 24 capabilities. TabloCart is sold separately and is gross margin accretive ASP and is  
 25 proving to be valuable solution to many of our acute care customers.

26 137. On May 4, 2023, Outset filed a quarterly report for the period ended March 31,  
 27 2023 on a Form 10-Q with the SEC (the "1Q23 10-Q"). The 1Q23 10-Q was signed by Defendants  
 28 Trigg and Ahmed and was accompanied by SOX Certifications made by Defendants Trigg and  
 29 Ahmed, wherein they attested to the accuracy of the 1Q23 10-Q.

30 138. In the 1Q23 10-Q, the Company affirmed its previously disclosed financial results  
 31 in the 1Q23 10-Q and highlighted the Company's sale practices, stating, in relevant part:

32 Tablo is cleared by the FDA for use in the hospital, clinic, or home setting. . . .

33 In late July 2022, the FDA cleared our 510(k) application of Tablo for patient use  
 34 in the home and we resumed marketing and shipping Tablo for home use. . . .

1 We primarily see our solutions through our direct sales organization, which covers  
 2 most major metropolitan markets in the United States. Our sales organization is  
 3 comprised of our capital sales team, responsible for generating new customer  
 4 demand for Tablo, and our clinical sales team, responsible for driving utilization  
 and fleet expansion of Tablo consoles to existing customer sites. . . .

5 We believe the ability to leverage one team to serve both markets will result in  
 6 significant productivity and cost optimization as we continue to scale our business.

7 139. On June 30, 2023, Outset published its 2023 ESG Report on its website, stating,  
 in relevant part:

8 Outset has adopted an ethical marketing procedure that defines acceptable  
 9 and unacceptable advertising, sales support, training, and other promotional  
 10 practices for Outset medical devices in the United States. Included in this  
 11 procedure is Outset's policy that all claims with respect to Outset products  
 12 must be consistent with approved labeling, with the data submitted to the FDA  
 to obtain 510(k) clearance and/or substantiated with appropriate evidence (i.e.,  
 13 instructions-for-use, verification and validation testing, clinical study report, or  
 any other report requiring a similar rigorous process of review and approval).

14 In addition, without exception, promotional material or statements made by  
 15 Outset sales representatives may not promote, discuss, or refer to uncleared,  
 16 unapproved, or off-label use. This means that all promotional activities may be  
 17 neither false nor misleading (either in terms of a specific product claim or the  
 overall net impression conveyed by the promotional material) and must comply  
 with all specific conditions of approval for the product being promoted.

18 140. The statements detailed above in ¶¶ 79-139 were materially false and misleading  
 19 when made because they failed to disclose material adverse facts about the Company's business,  
 20 operations, and prospects. Specifically, the Individual Defendants failed to disclose, *inter alia*,  
 21 that: (i) Outset was required to have prior 510(k) clearance from the FDA in order to receive  
 22 marketing authorization for TabloCart; (ii) Outset had not secured 510(k) clearance from the FDA  
 23 for TabloCart prior to marketing and selling TabloCart; (iii) as a result, Outset would be forced  
 24 to halt its shipments of TabloCart; (iv) Outset had falsely represented that continuous renal  
 25 replacement therapy ("CRRT") was a modality within the FDA-approved indications for Tablo;  
 26 (v) Outset lacked the sales team and processes to successfully scale up Tablo sales; (vi) Outset's  
 27 internal controls and risk oversight over, *inter alia*, its drug approvals, sales, and marketing were

inadequate, leading to the improper marketing of TabloCart and the unauthorized promotion of Tablo for CRRT, rendering Outset's SOX Certifications false and misleading when issued; (vii) as a result of the foregoing, Outset's reports and financial statements did not accurately or fairly present Outset's financial condition, revenue, or revenue growth as they relied on improper marketing practices and were the result of undisclosed, illicit, and unsustainable marketing tactics; and (viii) consequently, Outset's public statements regarding its business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

### **The Truth Begins to Emerge**

141. On July 7, 2023, the truth began to emerge when Outset filed a Form 8-K with the SEC and announced that it had received a Warning Letter from the FDA.

142. The Form 8-K disclosed that:

On July 6, 2023, Outset Medical, Inc. (the "Company") received a Warning Letter, dated July 5, 2023 (the "Warning Letter"), from the United States Food and Drug Administration (the "FDA").

As previously disclosed by the Company in its Annual Report on Form 10-K filed on February 13, 2023, the FDA issued an FDA Form-483 identifying four inspectional observations resulting from an FDA inspection that concluded on February 10, 2023. The Company provided its response plan to the FDA on March 3, 2023 and has since completed the associated remediation workstreams to fully address these observations.

The Warning Letter raises two additional observations. The first observation asserts that certain materials reviewed by the FDA and found on the Company's website promote continuous renal replacement therapy (CRRT), a modality outside of the current indications for the Tablo® Hemodialysis System. The Company believes this concern has been effectively addressed through labeling and promotional changes already underway.

The second observation asserts that the TabloCart with Prefiltration (the "TabloCart"), requires prior 510(k) clearance for marketing authorization. TabloCart, an accessory to the Tablo System, launched in the third quarter of 2022 and sales to date have not been material to the Company's financial results. The Company intends to work collaboratively with the FDA to resolve this observation, including potentially submitting a 510(k) on TabloCart.

1 The Warning Letter does not request the restriction of the manufacture, production  
2 or shipment of the Tablo System in the United States nor does it request the  
withdrawal of the Tablo System from the U.S. marketplace.

3 The Company intends to fully cooperate with the FDA, including by responding  
4 within 15 business days, to expeditiously and completely resolve the Warning  
5 Letter. The Company cannot, however, give any assurances that the FDA will be  
6 satisfied with the Company's actions taken in response to the matters raised in the  
Warning Letter. The Company also cannot give any assurances as to the timing of  
the resolution of such matters.

7 143. On this news, Outset's stock price fell \$1.20 per share, or nearly 6%, to close at  
8 \$19.26 per share on July 10, 2023, the next trading day.

9 144. On July 18, 2024, the FDA publicly released the Warning Letter to the public via  
10 its website. The Warning Letter, addressed to Defendant Trigg, stated, in relevant part:

11 During an inspection of your firm located at 3052 Orchard Drive in San Jose, CA  
12 on January 17, 2023, through February 10, 2023, investigators from the United  
13 States Food and Drug Administration (FDA) determined that your firm is a  
14 medical device manufacturer of the Tablo Hemodialysis System and TabloCart  
with Prefiltration. Under section 201(h) of the Federal Food, Drug, and Cosmetic  
15 Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are  
16 instruments, apparatuses, implements, machines, contrivances, implants, in vitro  
17 reagents, or other similar or related articles, including any component, part, or  
accessory, which are intended for use in the diagnosis of disease or other  
conditions or in the cure, mitigation, treatment, or prevention of disease, or to  
affect the structure or any function of the body.

18 We received responses from you dated March 3, 2023, concerning our  
19 investigators' observations noted on the Form FDA 483 (FDA 483), List of  
20 Inspectional Observations, that was issued to your firm. We address this response  
21 below, in relation to each of the noted violations, and any additional responses will  
be reviewed as part of your warning letter response.

## 22 **Unapproved Device Violations**

23 1. The TabloCart with Prefiltration is adulterated under section 510(f)(1)(B) of the  
24 Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved  
25 application for premarket approval (PMA) in effect pursuant to section 515(a) of  
the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational  
26 device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). The device  
is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your  
27 firm did not notify the agency of its intent to introduce the device into commercial

distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(i).

*You have not submitted any premarket notification to the Agency for the TabloCart with Prefiltration. However, the evidence and marketing materials reviewed at the inspection and found on your website [www.outsetmedical.com] on March 15, 2023, indicate that the TabloCart with Prefiltration is a device.* For example, your materials state that the TabloCart with Prefiltration is used for “prefiltration”; has “[t]hree customizable filter configurations [to] enable added filtration of carbon and sediment, depending on a facility’s incoming water quality”; and is intended to be used with your Tablo Hemodialysis System.

It appears that the TabloCart with Prefiltration could be classified under 21 CFR 876.5665 (Water purification system for hemodialysis), a Class II device type subject to premarket notification:

“(a) Identification. A water purification system for hemodialysis is a device that is intended for use with a hemodialysis system and that is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. This generic type of device may include a water softener, sediment filter, carbon filter, and water distillation system.”

TabloCart with Prefiltration appears to meet this definition because:

- It is intended to be used with a Hemodialysis System
- It is intended to remove organic and inorganic substances from water used to dilute dialysate concentrate to form dialysate

The TabloCart with Prefiltration is intended to improve the incoming water quality and lower the pressure specifications for the Tablo Hemodialysis System to include water that exceeds (b)(4). Inadequate filtration of lower quality incoming water may result in adverse effects arising from organic and inorganic contaminants that might be found in improperly prepared dialysis fluid. *As noted above, your firm is marketing this device without clearance or premarket approval.*

For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the FDA [21 CFR 807.81(b)]. The kind of information that your firm needs to submit in order to obtain approval or clearance for the devices is described on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm>. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

2. The Tablo Hemodialysis System is adulterated under section 510(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). The device is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(i).

You currently have clearance for the Tablo Hemodialysis System under K223248 for the following indications:

“The Tablo Hemodialysis System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility or in the home. Treatments must be administered under a physician’s prescription and observed by a trained individual who is considered competent in the use of the device. Treatment types available include Intermittent Hemodialysis (IHD), Sustained Low Efficiency Dialysis (SLED/ SLEDD), Prolonged Intermittent Renal Replacement Therapy (PIRRT), and Isolated Ultrafiltration.”

However, the evidence reviewed at the inspection and marketing materials found on your website [[www.outsetmedical.com](http://www.outsetmedical.com)] on May 11, 2023, show promotion of the Tablo Hemodialysis System for continuous renal replacement therapy (CRRT) treatment. For example, materials on your website state that two large hospitals converted to a program consisting solely of the Tablo Hemodialysis System and state, “This major conversion eliminated the need for several types of dialysis machines for different clinical needs, including intermittent hemodialysis (IHD) in the dialysis unit and continuous renal replacement therapy (CRRT) in critical care.” Other materials on your website state that multiple hospitals who had established CRRT treatment programs “converted those CRRT programs over to Tablo with Extended Therapy” and states, “They also replaced their CRRT machines with Tablo with XT...”

***We evaluated the FDA databases and did not find documentation that you have a cleared 510(k) or a premarket notification in-house for an Indications for Use that includes CRRT treatment.*** In addition, we note that during review of K223248, you confirmed that CRRT is distinct from the cleared indications for use, device specifications, and treatment modalities for the Tablo Hemodialysis System, and that PIRRT transitions to CRRT at **(b)(4)** of use. Patients who require CRRT are typically hospitalized with acute illness resulting in acute kidney injury and possible severe hemodynamic instability, and the devices that provide CRRT treatment have unique features to enable continuous treatment (> 24 hours) for this patient population. Systems that cannot safely and reliably perform CRRT raise

1 serious public health concerns when used for CRRT treatment, because failure of  
 2 dialysis systems performing CRRT may result in fluid and electrolyte imbalances,  
 3 inadequate ultrafiltration, infection, and patient harm/death. This change  
 4 represents a significant modification outside the scope of the K223248 clearance  
 5 that could significantly affect safety or effectiveness, resulting in a new device  
 6 such that a separate, additional 510(k) premarket notification must be submitted  
 7 [see 21 CFR 807.81(a)(3)(i)]. ***Thus, the sale of the Tablo Hemodialysis System***  
 8 ***for CRRT is unlawful.***

9 For further explanation on the need for a new 510(k) for labeling changes and  
 10 claims, the following information is from guidance document, Deciding When to  
 11 Submit a 510(k) for a Change to an Existing Device. The guidance states “most  
 12 labeling changes that affect the substance, meaning, or scope of the indications for  
 13 use could significantly affect safety or effectiveness and will require submission  
 14 of a new 510(k).” Your firm’s sale of the Tablo Hemodialysis System for CRRT  
 15 treatment constitutes a change to the scope of the indications for use and  
 16 significantly affects the safety or effectiveness of the device. Accordingly, this  
 17 change requires the submission of a new 510(k).

18 For a device requiring premarket approval, the notification required by section  
 19 510(k) is deemed satisfied when a PMA is pending before the FDA [21 CFR  
 20 807.81(b)]. The kind of information that your firm needs to submit in order to  
 21 obtain approval or clearance for the devices is described on the Internet  
 22 at  
 23 [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMark](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm)  
 24 [et YourDevice/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm). The FDA will evaluate the information that your firm  
 25 submits and decide whether the product may be legally marketed.

26 Your response dated March 3, 2023, does not address these violations.

27 (Emphasis added).

28 145. On August 2, 2023, after market hours, Outset issued a press release announcing  
 its financial results for the second quarter of 2023, wherein Outset announced that it was pausing  
 the shipment of TabloCart pending 510(k) clearance from the FDA. The press release stated, in  
 relevant part:

The Company also announced it has paused the shipment of TabloCart with  
 Prefiltration, an accessory for the Tablo System, pending the Food and Drug  
 Administration’s clearance of a 510(k) the company plans to submit later this  
 month.

“Since receiving the Warning Letter on July 6, we have made the decision to file  
 a 510(k) for TabloCart with Prefiltration and pause distribution of the product until

1 a 510(k) clearance has been granted,” added Trigg. “As we look ahead to the  
2 second half of the year, we expect our strong momentum both in the acute and  
home end markets to continue to drive the business.”

3 146. The same press release also revealed that the Company was expecting its 2023  
4 revenue to be on the lower range of its previous estimate due to the hold in TabloCart shipments:

5 Outset reiterated its 2023 revenue guidance range of \$144 million to \$150 million,  
6 and now expects to be at the low end of this range as a result of the shipment pause  
7 for TabloCart with Prefiltration. The Company reaffirmed its gross margin  
guidance for the year to be in the low-20% range, exiting the fourth quarter in the  
mid-20% range.

8 147. On August 2, 2023, Outset filed its quarterly report for the period ended June 30,  
9 2023 on a Form 10-Q with the SEC (the “2Q23 10-Q”). The 2Q23 10-Q affirmed the pause on  
10 TabloCart shipments, but assured investors that Tablo would continue to drive the Company’s  
11 business, stating, in relevant part:

12 Although we evaluated TabloCart with Prefiltration prior to marketing and  
13 distributing the product and concluded that no marketing authorization was  
14 necessary, we have paused distribution of TabloCart with Prefiltration pending the  
FDA’s review and clearance of the 510(k) application we plan to submit. . . .

15 Driving adoption of Tablo in the acute care setting has been our primary focus to  
16 date. We have invested in growing our economic and clinical evidence, built a  
17 veteran sales and clinical support team with significant expertise, and implemented  
18 a comprehensive training and customer experience program. Our experience in the  
acute care market has demonstrated Tablo’s clinical flexibility and operational  
19 versatility, while also delivering meaningful cost savings to the providers. We plan  
20 to continue leveraging our commercial infrastructure to broaden our installed base  
in the acute care market, as well as driving utilization and fleet expansion with our  
existing customers.

21 148. On this news, Outset’s stock price fell \$1.97 per share, or approximately 10.2%,  
22 to close at \$17.39 per share on August 3, 2023.

23 149. On October 12, 2023, Outset issued a press release announcing its preliminary  
24 third-quarter financial results, reporting that:

25 Preliminary revenue for the third quarter was \$30.4 million, a 9% increase over  
26 revenue of \$27.8 million in the third quarter of 2022. Outset now expects revenue  
27 for 2023 to be approximately \$130 million. Preliminary gross margin for the third

1 quarter was 23.6%, or 25.6% on a non-GAAP basis, compared to 16.4% on a non-  
2 GAAP basis in the third quarter of 2022. Total cash, including restricted cash, cash  
equivalents and short-term investments, was \$197 million as of Sept. 30, 2023.

3 150. In the same press release, Defendant Trigg is quoted as stating “[g]rowth in the  
4 quarter was dampened by a larger-than-expected impact in the field from the recent FDA warning  
5 letter, and early signs of a more cautious outlook on capital spending that we see as a headwind  
6 continuing through the fourth quarter.”

7 151. On this news, the Company’s stock price dropped by \$3.38 per share, or nearly  
8 50%, to close at \$3.39 per share on October 13, 2023.

9 152. On November 7, 2023, Outset issued a press release announcing its financial  
10 results for the third quarter of 2023, which stated, in relevant part:

11 Revenue for the third quarter was \$30.4 million, a 9% increase over revenue of  
12 \$27.8 million in the third quarter of 2022, and gross margin was 23.6%, or 25.6%  
13 on a non- GAAP basis, compared to 16.4% on a non-GAAP basis in the third  
quarter of 2022. . . .

#### 14 **Full Year 2023 Financial Guidance**

15 Outset reiterated its 2023 revenue guidance of approximately \$130 million and its  
16 previous gross margin guidance for the year to be in the low-20% range, exiting  
the fourth quarter in the mid-20% range.

17 153. On November 7, 2023, during an accompanying earnings call hosted to discuss  
18 the Company’s financial results for the third quarter of 2023, the Company revealed that:

19 [W]e’re still facing and would expect to face in Q4 some of the competitive  
20 activity around TabloCart not being available by our choice and some competitive  
21 noise making around the other aspect of the warning letter around some case  
22 studies that were on our website, we feel that we have fully satisfied the FDA's  
concerns around the website. And, of course, we’ve filed an 510(k) on TabloCart.

23 154. On November 8, 2023, Outset filed its quarterly report for the period ended  
24 September 30, 2023 on a Form 10-Q with the SEC (the “Q323 10-Q”). The 3Q23 10-Q confirmed  
25 the Company’s third quarter financial results and discussed the TabloCart shipment hold, as well  
26 as the Company’s sales practices, stating, in relevant part:

1 First, although we evaluated TabloCart with Prefiltration prior to marketing and  
 2 distributing the product and concluded that no marketing authorization was  
 3 necessary, we paused distribution of TabloCart with Prefiltration pending the  
 4 FDA's review and clearance of a 510(k) application. . . .

5 We primarily sell our solutions through our direct sales organization, which covers  
 6 most major metropolitan markets in the United States. Our sales organization is  
 7 comprised of our capital sales team, responsible for generating new customer  
 8 demand for Tablo, and our clinical sales team, responsible for driving utilization  
 9 and fleet expansion of Tablo consoles at existing customer sites. In addition, our  
 10 field service team provides maintenance services and product support to Tablo  
 11 customers. Our field sales and service teams represent 45% of our total full-time  
 12 employees as of September 30, 2023. The same sales organization and field  
 13 service team drive Tablo penetration in both the acute and home markets. We  
 14 believe the ability to leverage one team to serve both markets will result in  
 15 significant productivity and cost optimization as we continue to scale our business.

16 155. On this news, the Company's stock price declined \$0.62 per share, or  
 17 approximately 14.4%, to close at \$3.69 per share on November 8, 2024.

18 156. On January 8, 2024, Outset issued a press release announcing its unaudited  
 19 financial results for the fourth quarter and full year 2023, along with its revenue and gross margin  
 20 guidance for 2024, which reported that "revenue for 2023 [was] \$130 million, a 13% increase  
 21 compared to \$115 million in 2022," and provided 2024 guidance, stating in relevant part:

22 **2024 Guidance**

23 Outset expects 2024 revenue to be between \$145 million to \$153 million, growing  
 24 12% to 18% over unaudited revenue for 2023 based on the assumptions previously  
 25 disclosed. Non-GAAP gross margin is expected to expand to the low-30% range  
 26 for the full year 2024 and exit the year in the mid-30% range for the fourth quarter  
 27 of 2024.

28 157. On February 21, 2024, Outset issued a press release announcing its official  
 financial results for the fourth quarter and full year of 2023 and providing full-year 2024 guidance,  
 stating in relevant part:

- Recorded net revenue of \$30.5 million in the fourth quarter, bringing 2023 revenue to \$130.4 million, a 13% increase compared to \$115.4 million in 2022.

- Increased gross margin in the fourth quarter by nearly 900 basis points from the prior-year period. Fourth quarter gross margin reached 25.3% (26.7% on a non- GAAP basis) compared to 16.5% (17.1% on a non- GAAP basis) in the fourth quarter of 2022. Gross margin for the full year was 22.2% (23.6% on a non- GAAP basis) compared to 15.5% (16.1% on a non-GAAP basis) in 2022. . . .

#### **Full Year 2024 Financial Guidance**

Outset reaffirmed its previously provided guidance for 2024, including revenue of \$145 million to \$153 million, growing 12% to 18% over 2023, and non-GAAP gross margin in the low-30% range for 2024, exiting the year in the mid-30% range for the fourth quarter.

158. On February 21, 2024, Outset filed its annual report for 2023 on a Form 10- K with the SEC (the “2023 10-K”). The 2023 10-K was signed by Defendants Trigg, Ahmed, Grossman, Drexler, Hackett, Hinrichs, Jones, Saia, and Szyman. The 2023 10-K was also accompanied by SOX Certifications made by Defendants Trigg and Ahmed, wherein they attested to the accuracy of the 2023 10-K.

159. The 2023 10-K highlighted Tablo and the Company’s sales, stating, in relevant part:

Driving adoption of Tablo in the acute setting has been our primary focus since Tablo’s clearance by the FDA for use in an acute or chronic care facility in September 2014. We have invested in growing our economic and clinical evidence, built veteran field service, sales and clinical support teams with significant expertise, and implemented a comprehensive training and customer experience program. Our experience in the acute market has demonstrated Tablo’s clinical flexibility and operational versatility, while also delivering meaningful cost savings to the providers.

We plan to continue leveraging our commercial infrastructure, including our sales, field service and marketing teams, to broaden our installed base in the acute care market, as well as driving utilization and fleet expansion with our existing customers. . . .

We primarily sell our solutions through our direct sales organization, which covers most major metropolitan markets in the United States. Our sales organization is comprised of our capital sales team, responsible for generating new customer demand for Tablo, and our clinical sales team, responsible for driving utilization and fleet expansion of Tablo at existing customer sites. In addition, our field service team provides maintenance services and product support to our customers.

1 Our field sales and service teams represent 48% of our total full-time employees  
2 as of December 31, 2023. The same sales organization and field service team drive  
3 Tablo penetration in both the acute and home markets. We believe the ability to  
4 leverage one team to serve both markets will result in significant productivity and  
5 cost optimization as we continue to scale our business. . . .

6 If we fail to retain our sales and marketing personnel, fail to increase our sales and  
7 marketing capabilities or develop broad awareness of Tablo in a cost-effective  
8 manner, we may not be able to generate revenue growth.

9 We have limited experience marketing and selling Tablo. We currently rely on our  
10 direct sales force to sell Tablo in the United States, and any failure to maintain,  
11 leverage and optimize our direct sales force will negatively affect our business,  
12 financial condition and results of operations. The members of our direct sales force  
13 are highly trained and possess substantial technical expertise, which we believe is  
14 critical in increasing adoption of Tablo.

15 160. On April 11, 2024, Outset filed a proxy statement on a Schedule 14A with the SEC  
16 (the “2024 Proxy Statement”). With respect to the Company’s internal controls and risk oversight,  
17 the 2024 Proxy Statement stated:

18 One of the key functions of our Board is informed oversight of our risk  
19 management process. Our Board’s role in risk oversight is consistent with our  
20 leadership structure, with management having day-to-day responsibility for  
21 assessing and managing our risk exposure and our Board actively overseeing  
22 management of our risks – both at the Board and committee level. The risk  
23 oversight process includes receiving regular reports from committees and  
24 management to enable our Board to understand our risk identification, risk  
25 management and risk mitigation strategies with respect to areas of potential  
26 material risk, including operations, information technology (including  
27 cybersecurity and data privacy), finance, legal, regulatory, strategic and  
28 reputational risks. Our Board focuses on the overall risks affecting us, and each of  
its standing committees has been delegated responsibility for oversight of specific  
risks that fall within its areas of responsibility. For example:

- Our Audit Committee is responsible for overseeing our major financial, legal and regulatory risk exposures, which spans a variety of areas including litigation, regulatory compliance, financial reporting and insurance, as well as data privacy, cybersecurity and other information technology risks. Our Audit Committee also oversees the steps management has taken to monitor and control such exposures, including guidelines and policies for assessing and managing risk and related compliance efforts. . . .

1 While each committee is responsible for evaluating certain risks and overseeing  
2 the management of such risks, the full Board is regularly informed through  
3 committee reports about such risks.

4 161. On May 6, 2024, Outset issued a press release announcing that the FDA granted  
5 510(k) clearance for TabloCart, stating, in relevant part, that “Outset has resumed distribution of  
6 TabloCart with prefiltration and has product available to ship to customers in the United States.”

7 162. On May 8, 2024, Outset issued a press release announcing its financial results for  
8 the first quarter of 2024, wherein the Company reported revenue of \$28.2 million, total gross  
9 profit of \$8.2 million, and a net loss of \$39.9 million for the first quarter.

10 163. The press release also assured investors that the Company was optimistic for the  
11 future, stating, in part:

12 With our recent 510(k) clearance for TabloCart with Prefiltration, 12th  
13 consecutive quarter of gross margin expansion and strong sales pipeline growth  
14 during the quarter, we are well positioned to capitalize on the \$11 billion U.S.  
15 dialysis market opportunity...Tablo’s uniquely compelling value proposition  
16 continues to resonate with acute- and homecare providers, with significant new  
17 customer wins in both settings during the quarter.” . . .

#### 18 **Full Year 2024 Financial Guidance**

19 Outset reaffirmed its previously provided guidance for 2024 including revenue of  
20 \$145 million to \$153 million, growing 12% to 18% over 2023, and non-GAAP  
21 gross margin in the low-30% range for the full year 2024, exiting the year in the  
22 mid-30% range for the fourth quarter.

23 164. On May 9, 2024, Outset filed its quarterly report for the period ended March 31,  
24 2024 on a Form 10-Q with the SEC (the “1Q24 10-Q”), which confirmed the previously disclosed  
25 financial results and stated, in relevant part:

26 Driving adoption of Tablo in the acute care setting has been our primary focus to  
27 date. We have invested in growing our economic and clinical evidence, built a  
28 veteran sales and clinical support team with significant expertise, and implemented  
a comprehensive training and customer experience program. Our experience in the  
acute care market has demonstrated Tablo’s clinical flexibility and operational  
versatility, while also delivering meaningful cost savings to the providers. We plan  
to continue leveraging our commercial infrastructure to broaden our installed base  
in the acute care market, as well as driving utilization and fleet expansion with our  
existing customers.

We primarily sell our solutions through our direct sales organization, which covers most major metropolitan markets in the United States. Our sales organization is comprised of our capital sales team, responsible for generating new customer demand for Tablo, and our clinical sales team, responsible for driving utilization and fleet expansion of Tablo at existing customer sites. In addition, our field service team provides maintenance services and product support to our customers. Our field sales and service teams represent 49% of our total full-time employees as of March 31, 2024. The same sales organization and field service team drive Tablo penetration in both the acute and home markets. We believe the ability to leverage one team to serve both markets will result in significant productivity and cost optimization as we continue to scale our business.

165. The statements detailed above in ¶¶ 145-164 were materially false and misleading when made because they failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, the Individual Defendants failed to disclose, *inter alia*, that: (i) Outset lacked the necessary sales team and processes to effectively scale Tablo sales; (ii) as a result, Outset's revenue growth would be negatively affected; (iii) Outset failed to maintain adequate internal controls over its drug approvals, sales, and marketing, among other things; and (iv) as a result of the foregoing, Outset's public statements regarding its business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

### **The Truth Fully Emerges**

166. On August 7, 2024, nearly ten months later, the truth was fully revealed when Outset issued a press release announcing its second-quarter 2024 financial results, wherein the Company revealed it significantly missed consensus estimates and was lowering its full-year 2024 revenue guidance by \$39 million at the endpoint. Specifically, the press release stated that:

[N]ew console placements were below our expectations and will be lower than we originally forecasted for the year. We are taking clear steps to improve our execution and grow the business over the long term to bring the benefits of Tablo to even more providers and dialysis patients. . . .

### **Second Quarter 2024 Financial Results**

Revenue for the second quarter was \$27.4 million compared to \$36.0 million in the second quarter of 2023, driven by a decline in product revenue to \$19.2 million.

1 Service and other revenue was \$8.2 million, an increase of 21.5% compared to  
 2 \$6.7 million in the second quarter of 2023. Recurring revenue from the sale of  
 3 Tablo cartridges and service increased by 24% as compared to the prior-year  
 4 period. Total gross profit was \$9.8 million, compared to \$7.7 million for the  
 second quarter of 2023. Total gross margin was 35.7%, compared to 21.4% in the  
 second quarter of 2023. . . .

#### 5 **Full Year 2024 Financial Guidance**

6 Outset now expects 2024 revenue to be approximately \$110 million, revised from  
 7 a prior range of \$145 million to \$153 million, and non-GAAP gross margin to be  
 8 in the low-to-mid 30% range, revised from prior guidance in the low-30% range  
 for 2024 and exiting the year in the mid-30% range for the fourth quarter. . . .

9 Given the depth and breadth of the sales team and process restructuring, we expect  
 10 it to take several quarters to fully implement and realize the many benefits that  
 11 will come from it. As we look ahead to the second half of the year, we now know  
 12 it will not be possible to execute this transformation given the expected  
 13 accompanying disruption while simultaneously delivering on the ramp we  
 previously forecasted. As a result, we expect the second half of 2024 will look  
 similar to the first half with expected revenue for the year of approximately \$110  
 million.

14 167. On this news, Outset's stock price fell \$2.33 per share, or approximately 68%, to  
 15 close at \$1.07 per share on August 8, 2024.

#### 16 **INSIDER TRADING DURING THE RELEVANT PERIOD**

17 168. During the Relevant Period, as a result of the Individual Defendants' above false  
 18 and misleading statements, the Company's share price was artificially inflated. During this time,  
 19 while in possession of material, non-public information, Individual Defendants Trigg, Ahmed,  
 20 Chambers, and Grossman ("Insider Trading Defendants") engaged in improper insider sales,  
 21 selling over 1 million shares and netting total proceeds of approximately \$35 million.

22 169. Defendant Trigg sold approximately 837,702 shares of Outset common stock  
 23 while in possession of material, non-public information and while the Company's stock price was  
 24 artificially inflated, totaling proceeds of approximately \$30,202,524.

25 170. As CEO, Defendant Trigg knew the truth about, *inter alia*, (a) TabloCart's  
 26 required prior 510(k) clearance from the FDA before it could receive marketing authorization; (b)  
 27 that Outset had not secured the necessary FDA clearance to market and sell the TabloCart; (c)

1 that, as a result, Outset would be required to halt the shipment of TabloCart; (d) that Outset had  
2 falsely represented CRRT as a modality within the FDA-approved indications for Tablo; and (e)  
3 that Outset lacked the necessary sales team and processes to successfully scale Tablo sales.

4 171. Defendant Ahmed sold approximately 40,983 shares of Outset common stock  
5 while in possession of material, non-public information and while the Company's stock price was  
6 artificially inflated, totaling proceeds of approximately \$514,065.

7 172. As CFO, Defendant Ahmed knew the truth about, *inter alia*, (a) TabloCart's  
8 required prior 510(k) clearance from the FDA before it could receive marketing authorization; (b)  
9 that Outset had not secured the necessary FDA clearance to market and sell the TabloCart; (c)  
10 that, as a result, Outset would be required to halt the shipment of TabloCart; (d) that Outset had  
11 falsely represented CRRT as a modality within the FDA-approved indications for Tablo; and (e)  
12 that Outset lacked the necessary sales team and processes to successfully scale Tablo sales.

13 173. Defendant Chambers sold approximately 66,908 shares of Outset common stock  
14 while in possession of material, non-public information and while the Company's stock price was  
15 artificially inflated, totaling proceeds of approximately \$3,385,038.

16 174. As CFO, Defendant Chambers knew the truth about, *inter alia*, (a) TabloCart's  
17 required prior 510(k) clearance from the FDA before it could receive marketing authorization; (b)  
18 that Outset had not secured the necessary FDA clearance to market and sell the TabloCart; (c)  
19 that, as a result, Outset would be required to halt the shipment of TabloCart; (d) that Outset had  
20 falsely represented CRRT as a modality within the FDA-approved indications for Tablo; and (e)  
21 that Outset lacked the necessary sales team and processes to successfully scale Tablo sales.

22 175. Defendant Grossman sold approximately 60,149 shares of Outset common stock  
23 while in possession of material, non-public information and while the Company's stock price was  
24 artificially inflated, totaling proceeds of approximately \$1,309,957.

25 176. As a Board member, Defendant Grossman knew the truth about, *inter alia*, (a)  
26 TabloCart's required prior 510(k) clearance from the FDA before it could receive marketing  
27 authorization; (b) that Outset had not secured the necessary FDA clearance to market and sell the  
28

1 TabloCart; (c) that, as a result, Outset would be required to halt the shipment of TabloCart; (d)  
2 that Outset had falsely represented CRRT as a modality within the FDA-approved indications for  
3 Tablo; and (e) that Outset lacked the necessary sales team and processes to successfully scale  
4 Tablo sales.

### 5 **DAMAGES TO OUTSET**

6 177. As a direct and proximate result of the Individual Defendants' misconduct, Outset  
7 has expended, and will continue to expend, significant sums of money.

8 178. Such expenditures include, but are not limited to, legal fees associated with  
9 defending against the Securities Class Action filed against the Company and Defendants Trigg,  
10 Chambers, and Ahmed and any internal investigations, and amounts paid to outside lawyers,  
11 accountants, and investigators in connection thereto, as well as payments of any fine or settlement  
12 amounts associated with the Company's violations.

13 179. These expenditures also include, but are not limited to, the costs associated with  
14 implementing measures to remediate the material weaknesses in the Company's internal controls  
15 with respect to financial reporting, public disclosures, and legal and regulatory compliance.

16 180. These losses also include, but are not limited to, substantial compensation, bonuses  
17 and benefits paid to the Individual Defendants who breached their fiduciary duties to the  
18 Company.

19 181. As a direct and proximate result of the Company's actions and misrepresentations  
20 and the Individual Defendants' breaches of fiduciary duties, Outset has suffered and will continue  
21 to suffer damage to its reputation and goodwill, along with a "liar's discount" that will negatively  
22 impact the Company's stock in the future.

### 23 **DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS**

24 182. Plaintiff brings this action derivatively in the right of and for the benefit of Outset  
25 to redress injuries suffered, and to be suffered, as a direct and proximate result of the Individual  
26 Defendants' breaches of fiduciary duties and violations of federal law as alleged herein.

27 183. Outset is named solely as a nominal party in this action. This is not a collusive  
28

1 action to confer jurisdiction on this Court that it would otherwise not have.

2 184. Plaintiff is an owner of Outset stock and has been a continuous shareholder of  
3 Company stock at all relevant times. Plaintiff will adequately and fairly represent the interests of  
4 the Company in enforcing and prosecuting its rights and has retained counsel competent and  
5 experienced in derivative litigation.

6 185. At the time this suit was filed, the Board consisted of Defendants Trigg,  
7 Grossman, Drexler, Hackett, Saia (the “Director Defendants”), as well as non-parties Brett T.  
8 Lang (“Lang”) and Kevin O’Boyle (“O’Boyle”). Plaintiff is required to show that a majority, *i.e.*  
9 four, Board members cannot exercise independent objective judgment about whether to bring this  
10 action.

11 186. Plaintiff did not make a demand on the Board to institute this action. Such a  
12 demand would be a futile, wasteful, and useless act, because, as set forth below, all of the Director  
13 Defendants are incapable of making an independent and disinterested decision to institute and  
14 vigorously prosecute this action because they face a substantial likelihood of liability.

15 187. Each of the Director Defendants either knew or should have known of the false  
16 and misleading statements that were issued on the Company’s behalf and took no steps in a good  
17 faith effort to prevent or remedy the situation.

18 188. Each of the Director Defendants approved and/or permitted the wrongs alleged  
19 herein to have occurred and participated in efforts to conceal or disguise those wrongs from the  
20 Company’s stockholders or recklessly and/or with gross negligence disregarded the wrongs  
21 complained of herein and are therefore not disinterested parties.

22 189. Moreover, the Director Defendants willfully ignored, or recklessly failed to  
23 inform themselves of, the obvious problems with the Company’s internal controls, practices, and  
24 procedures and failed to make a good faith effort to correct the problems or prevent their  
25 recurrence.

26 190. The Director Defendants are not disinterested or independent because each of the  
27 Director Defendants is named as a defendant, and faces significant personal liability, in the

1 Securities Class Action based on substantially the same wrongdoing as alleged herein, specifically  
2 issuing materially false and misleading statements during the Relevant Period.

3 191. The acts complained of herein constitute violations of fiduciary duties owed by  
4 Outset's officers and directors, and these acts are incapable of ratification.

5 192. Demand is futile as to Defendant Trigg for the additional reasons that follow.  
6 Defendant Trigg is, and was at all relevant times, an employee who derives substantial  
7 compensation from Outset, as detailed above. The lack of independence and the financial benefits  
8 received by Defendant Trigg renders her incapable of impartially considering a demand to  
9 commence and vigorously prosecute this action. Thus, as the Company admits, Defendant Trigg  
10 is not an independent director. Defendant Trigg also solicited the false and misleading 2021, 2022,  
11 2023, and 2024 Proxy Statements, which led to, *inter alia*, shareholders voting to reelect several  
12 of the Individual Defendants to the Board, thereby allowing them to continue breaching their  
13 fiduciary duties to the Company. Defendant Trigg was ultimately responsible for Outset's 2021,  
14 2022, and 2023 10-Ks and all of the false and misleading SOX certifications which she signed.  
15 Defendant Trigg, while in possession of material non-public information, sold approximately  
16 837,702 shares of the Company's stock, netting proceeds of approximately \$30.2 million,  
17 demonstrating her motive in facilitating and participating in the misleading statements and  
18 making her subject to disgorgement. Defendant Trigg is named as a defendant in the Securities  
19 Class Action and faces significant personal liability based on substantially the same wrongdoing  
20 as alleged herein. As such, Defendant Trigg cannot independently consider any demand to sue  
21 herself for breaching her fiduciary duties and thus, demand is futile.

22 193. Demand is futile as to Defendant Grossman for the additional reasons that follow.  
23 Defendant Grossman derives substantial compensation from Outset, as detailed above. Defendant  
24 Grossman serves as a member of the Compensation Committee and the Corporate Governance  
25 Committee. Defendant Grossman also solicited the false and misleading 2021, 2022, 2023, and  
26 2024 Proxy Statements, which led to, *inter alia*, shareholders voting to reelect several of the  
27 Individual Defendants to the Board, thereby allowing them to continue breaching their fiduciary  
28

1 duties to the Company. Defendant Grossman also signed Outset's false and misleading 2021,  
2 2022, and 2023 10-Ks. Defendant Grossman, while in possession of material non-public  
3 information, sold approximately 60,149 shares of the Company's stock, netting proceeds of  
4 approximately \$1,309,957, demonstrating his motive in facilitating and participating in the  
5 misleading statements and making him subject to disgorgement. As such, Defendant Grosman  
6 cannot independently consider any demand to sue himself for breaching his fiduciary duties and  
7 thus, demand is futile.

8 194. Demand is futile as to Defendant Hackett for the additional reasons that follow.  
9 Defendant Hackett derives substantial compensation from Outset, as detailed above. Defendant  
10 Hackett serves as Chair of the Corporate Governance Committee and as a member of the Audit  
11 Committee. Defendant Hackett also solicited the false and misleading 2021, 2022, 2023, and 2024  
12 Proxy Statements, which led to, *inter alia*, shareholders voting to reelect several of the Individual  
13 Defendants to the Board, thereby allowing them to continue breaching their fiduciary duties to  
14 the Company. Defendant Hackett also signed Outset's false and misleading 2020, 2021, 2022, and  
15 2023 10-Ks. As such, Defendant Hackett cannot independently consider any demand to sue  
16 himself for breaching his fiduciary duties and thus, demand is futile.

17 195. Demand is futile as to Defendant Drexler for the additional reasons that follow.  
18 Defendant Drexler derives substantial compensation from Outset, as detailed above. Defendant  
19 Drexler serves as a member of the Compensation Committee and Chair of the Corporate  
20 Governance Committee. Defendant Drexler also solicited the false and misleading 2021, 2022,  
21 2023, and 2024 Proxy Statements, which led to, *inter alia*, shareholders voting to reelect several  
22 of the Individual Defendants to the Board, thereby allowing them to continue breaching their  
23 fiduciary duties to the Company. Defendant Drexler also signed Outset's false and misleading  
24 2020, 2021, 2022, and 2023 10-Ks. As such, Defendant Drexler cannot independently consider  
25 any demand to sue himself for breaching his fiduciary duties and thus, demand is futile.

26 196. Demand is futile as to Defendant Saia for the additional reasons that follow.  
27 Defendant Saia derives substantial compensation from Outset, as detailed above. Defendant Saia

1 also serves as a member of the Audit Committee. Defendant Saia also solicited the false and  
2 misleading 2022, 2023, and 2024 Proxy Statements, which led to, *inter alia*, shareholders voting  
3 to reelect several of the Individual Defendants to the Board, thereby allowing them to continue  
4 breaching their fiduciary duties to the Company. Defendant Saia also signed Outset's false and  
5 misleading 2021, 2022, and 2023 10-Ks. As such, Defendant Saia cannot independently consider  
6 any demand to sue himself for breaching his fiduciary duties and thus, demand is futile.

7 197. Additionally, demand is futile as to Defendants Hackett and Saia because they  
8 served as members of the Audit Committee at all relevant times. Pursuant to the Audit  
9 Committee's Charter, the purpose of the Audit Committee is to assist the Board in fulfilling its  
10 oversight responsibilities related to, *inter alia*, accounting, legal, regulatory, and public disclosure  
11 requirements. During the Relevant Period, Defendants Hackett and Saia violated the Audit  
12 Committee Charter by engaging in or permitting the Company to engage in the dissemination of  
13 materially false and misleading statements to the public and to facilitate the Individual  
14 Defendants' violations of law, including violations of the Exchange Act and breaches of fiduciary  
15 duty; failed to adequately exercise their risk management and risk assessment functions; and  
16 failed to ensure adequate Board oversight of the Company's internal control over financial  
17 reporting, disclosure controls and procedures, and the Code of Conduct. Thus, Defendants  
18 Hackett and Saia were responsible for knowingly or recklessly causing and/or allowing the  
19 improper statements to be released to the public, are not independent or disinterested, and thus,  
20 demand is futile as to them.

21 198. The Director Defendants, as members of the Board, were and are subject to the  
22 Company's Code of Conduct. The Code of Conduct goes well beyond the basic fiduciary duties  
23 required by applicable laws, rules, and regulations, requiring the Directors to also adhere to the  
24 Company's standards of business conduct. The Director Defendants violated the Code of Conduct  
25 because they knowingly or recklessly participated in making and/or causing the Company to make  
26 the materially false and misleading statements alleged herein. Because the Director Defendants  
27 violated the Code of Conduct, they face a substantial likelihood of liability for breaching their  
28

1 fiduciary duties, and therefore demand upon them is futile.

2 199. All of the Board's current members derive substantial revenue from the  
3 Company, control the Company, and are indebted to each other. These conflicts of interest have  
4 precluded the Board's current members from calling into question the Director Defendants'  
5 conduct.

6 200. Importantly, none of the Board's current members have taken remedial action to  
7 redress the conduct alleged herein. The Director Defendants have benefitted from the wrongs  
8 alleged herein and have engaged therein to preserve their positions of control and the prerequisites  
9 thereof and are incapable of exercising independent objective judgment in deciding whether to  
10 bring this action.

11 201. The Director Defendants' conduct described herein and summarized above could  
12 not have been the product of legitimate business judgment as it was based on bad faith and  
13 intentional, reckless, or disloyal misconduct. Thus, none of the directors can claim exculpation  
14 from their violations of duty pursuant to the Company's charter. As a majority of the directors  
15 face a substantial likelihood of liability, they are self-interested in the transactions challenged  
16 herein. They cannot be presumed to be capable of exercising independent and disinterested  
17 judgment about whether to pursue this action on behalf of the shareholders of the Company.  
18 Accordingly, demand is excused as being futile.

19 202. The Individual Defendants may also be protected against personal liability for  
20 their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and  
21 officers' liability insurance if they caused the Company to purchase it for their protection with  
22 corporate funds i.e., monies belonging to the stockholders of Outset. If there is a directors' and  
23 officers' liability insurance policy covering the Individual Defendants, it may contain provisions  
24 that eliminate coverage for any action brought directly by the Company against the Individual  
25 Defendants, known as, inter alia, the "insured-versus-insured exclusion." As a result, if the  
26 Director Defendants were to sue themselves or certain officers of Outset, there would be no  
27 directors' and officers' insurance protection. Accordingly, the Director Defendants cannot be

1 expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action  
 2 is brought, such insurance coverage, if such an insurance policy exists, will provide a basis for  
 3 the Company to effectuate a recovery. Thus, demand on the Director Defendants is futile and,  
 4 therefore, excused. If there is no directors' and officers' liability insurance, then the directors will  
 5 not cause Outset to sue the Defendants named herein, since, if they did, they would face a large  
 6 uninsured individual liability. Accordingly, demand is futile in that event as well.

7 203. Accordingly, each of the Director Defendants, and at least a majority of them,  
 8 cannot reasonably consider a demand with the requisite disinterestedness and independence.  
 9 Indeed, any pre-suit demand upon the Director Defendants is futile and, therefore, excused.

### 10 **CLAIM I**

#### 11 ***Against the Individual Defendants for Violations of Section 14(a) of the Exchange Act***

12 204. Plaintiff incorporates by reference and realleges each and every allegation set forth  
 13 above, as though fully set forth herein.

14 205. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that: “[i]t shall  
 15 be unlawful for any person, by use of the mails or by any means or instrumentality of interstate  
 16 commerce or of any facility of a national securities exchange or otherwise, in contravention of  
 17 such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public  
 18 interest or for the protection of investors, to solicit or to permit the use of his name to solicit any  
 19 proxy or consent or authorization in respect of any security (other than an exempted security)  
 20 registered pursuant to section 12 of this title [15 U.S.C. § 781].”

21 206. Rule 14a-9, provides that no proxy statement shall contain “any statement which,  
 22 at the time and in the light of the circumstances under which it is made, is false or misleading  
 23 with respect to any material fact, or which omits to state any material fact necessary in order to  
 24 make the statements therein not false or misleading.” 17 C.F.R. § 240.14a-9.

25 207. The Individual Defendants violated Section 14(a) of the Exchange Act and Rule  
 26 14a-9 promulgated thereunder.

208. Under the direction and watch of the Individual Defendants, the 2021, 2022, 2023, and 2024 Proxy Statements (the “Proxy Statements”) failed to disclose, *inter alia*, that: (i) Outset was required to have prior 510(k) clearance from the FDA in order to receive marketing authorization for TabloCart; (ii) Outset had not secured 510(k) clearance from the FDA for TabloCart prior to marketing and selling TabloCart; (iii) as a result, Outset would be forced to halt its shipments of TabloCart; (iv) Outset had falsely represented that continuous renal replacement therapy (“CRRT”) was a modality within the FDA-approved indications for Tablo; (v) Outset lacked the sales team and processes to successfully scale up Tablo sales; (vi) Outset’s internal controls and risk oversight over, *inter alia*, its drug approvals, sales, and marketing were inadequate, leading to the improper marketing of TabloCart and the unauthorized promotion of Tablo for CRRT, rendering Outset’s SOX Certifications false and misleading when issued; (vii) as a result of the foregoing, Outset’s reports and financial statements did not accurately or fairly present Outset’s financial condition, revenue, or revenue growth as they relied on improper marketing practices and were the result of undisclosed, illicit, and unsustainable marketing tactics; and (viii) consequently, Outset’s public statements regarding its business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

209. The misrepresentations and omissions in the Proxy Statements were material to Outset stockholders, specifically in voting on matters set forth for shareholder determination in the Proxy Statements, including, but not limited to, the reelection of certain Director Defendants.

For instance:

- The materially false and misleading statements in the 2021 Proxy Statement induced shareholders to vote for the reelection of Defendants Trigg and Drexler to the Board, allowing them to continue breaching their fiduciary duties to the Company.
- The materially false and misleading statements in the 2022 Proxy Statement induced shareholders to vote for the reelection of Defendants Grossman and

Hackett to the Board, allowing them to continue breaching their fiduciary duties to the Company.

- The materially false and misleading statements in the 2023 Proxy Statement induced shareholders to vote for the reelection of Defendants Saia, Hinrichs, and Szyman to the Board, allowing them to continue breaching their fiduciary duties to the Company.
- The materially false and misleading statements in the 2024 Proxy Statement induced shareholders to vote for the reelection of Defendants Drexler, Jones, and Trigg to the Board, allowing them to continue breaching their fiduciary duties to the Company.

210. The Company was damaged as a result of the Individual Defendants' material misrepresentations and omissions.

211. Plaintiff, on behalf of Outset, has no adequate remedy at law.

## **CLAIM II**

### ***Against the Individual Defendants for Breach of Fiduciary Duties***

212. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

213. Each Individual Defendant owed to Outset the fiduciary duty to exercise candor, good faith, fair dealing, and loyalty in the management and administration of Outset's business and affairs, particularly with respect to issues as fundamental as public disclosures.

214. Each of the Individual Defendants violated and breached his or her fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

215. The Individual Defendants' conduct set forth herein was due to their intentional, reckless, or negligent breach of the fiduciary duties they owed to the Company and to protect the rights and interests of Outset's shareholders.

1           216. The Individual Defendants knowingly or recklessly made untrue statements and/or  
2 permitted the Company's public filings, disclosures, and statements to misleadingly report the  
3 Company's overall business, operations, and prospects.

4           217. The Individual Defendants had actual or constructive knowledge that they caused  
5 the Company to engage in fraudulent schemes set forth herein and to fail to maintain adequate  
6 internal controls.

7           218. The Individual Defendants had actual knowledge of the misrepresentations and  
8 omissions of material facts set forth herein, or acted with reckless disregard for the truth, in that  
9 they failed to disclose such facts, even though such facts were available to them. Such material  
10 misrepresentations and omissions were committed for the purpose and effect of artificially  
11 inflating the price of Outset's securities. As such, the Individual Defendants' intentionally or  
12 recklessly breached or disregarded their fiduciary duties to protect the rights and interests of  
13 Outset.

14           219. Four of the Individual Defendants engaged in insider sales during the Relevant  
15 Period while the stock was artificially inflated, netting millions of dollars in proceeds for  
16 themselves.

17           220. These actions were not a good-faith exercise of prudent business judgment to  
18 protect and promote the Company's corporate interests.

19           221. As a direct and proximate result of the Individual Defendants' breaches of their  
20 fiduciary obligations, Outset has sustained and continues to sustain significant monetary damages  
21 as well as reputational harm and damage to the share price of the Company's stock. Such damages  
22 include costs of defending itself in the Securities Class Action and exposing the Company to  
23 millions of dollars in potential class-wide damages.

24           222. As a result of the misconduct alleged herein, the Individual Defendants are liable  
25 to the Company.

26           223. Plaintiff, on behalf of Outset, has no adequate remedy at law.  
27  
28

**CLAIM III**

***Against the Individual Defendants for Aiding and Abetting Breach of Fiduciary Duty***

224. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

225. By encouraging and accomplishing the illegal and improper transactions alleged herein and concealing them from the public, the Individual Defendants have encouraged, facilitated, and advanced their breach of their fiduciary duties.

226. In so doing, the Individual Defendants have each aided and abetted, conspired, and schemed with one another to breach their fiduciary duties, waste the Company's corporate assets, and engage in the illegal conduct complained of herein.

227. Plaintiff, on behalf of Outset, has no adequate remedy at law.

**CLAIM IV**

***Against the Individual Defendants for Waste of Corporate Assets***

228. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

229. By failing to properly consider the interests of the Company and its public shareholders, the Individual Defendants have caused Outset to waste valuable corporate assets. Specifically, the Individual Defendants have caused Outset to incur many millions of dollars of legal liability and/or costs to defend unlawful actions, to engage in internal investigations, and to lose financing from investors and business from future customers who no longer trust the Company and its products. Moreover, the Individual Defendants caused the Company to pay the Individual Defendants excessive salaries and fees, to the detriment of the shareholders and the Company.

230. The issuance of false and misleading statements by the Individual Defendants was continuous, connected, and ongoing through the Relevant Period and resulted in continuous, connected, and ongoing harm to Outset

231. As a result of the waste of corporate assets, the Individual Defendants are each liable to the Company.

232. Plaintiff, on behalf of Outset, has no adequate remedy at law.

**CLAIM V**

***Against the Individual Defendants for Unjust Enrichment***

233. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

234. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Outset.

235. The Individual Defendants either benefitted financially from the improper conduct, or received bonuses, stock options, or similar compensation from Outset that was tied to the performance or artificially inflated valuation of Outset, or received compensation or other payments that were unjust in light of the Individual Defendants' bad faith conduct.

236. Plaintiff, as a shareholder and a representative of Outset, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits, including from insider transactions, the redemption of preferred stock, benefits, and other compensation, including any performance-based or valuation-based compensation, obtained by the Individual Defendants due to their wrongful conduct and breach of their fiduciary and contractual duties.

237. Plaintiff, on behalf of Outset, has no adequate remedy at law.

**CLAIM VI**

***Against the Individual Defendants for Abuse of Control***

238. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

239. The Individual Defendants misconduct alleged herein constituted an abuse of their control over the Company, for which they are legally liable.

240. As a direct and proximate result of the Individual Defendants' abuse of control, the Company has sustained substantial damages.

241. Plaintiff, on behalf of Outset, has no adequate remedy at law.

**CLAIM VII**

***Against the Insider Trading Defendants for Misappropriation of Material, Non-Public Information***

242. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

243. At the time that the Insider Trading Defendants sold their Outset stock, they knew the material, non-public information described above and knew such information was proprietary, non-public information concerning the Company's financial condition and future business prospects. It was a proprietary asset belonging to the Company, which the Insider Trading Defendants misappropriated to their own benefit when they sold Outset stock.

244. The Insider Trading Defendants sold stock motivated, in whole or in part, by the substance of such information.

245. The Insider Trading Defendants' sale of stock while in possession and control of this material, adverse, non-public information was a breach of their fiduciary duties of loyalty and good faith.

246. Since the use of the Company's proprietary information for their own gain constitutes a breach of the Insider Trading Defendants' fiduciary duties, any profits made by the Insider Trading Defendants as a result should be disgorged. The Company is entitled to the imposition of constructive trust on any profits the Insider Trading Defendants obtained thereby.

247. Plaintiff, on behalf of Outset, has no adequate remedy at law.

**CLAIM VIII**

***Against Defendants Trigg, Ahmed, and Chambers for Contribution Under 21D and 10(b) of the Exchange Act***

248. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

249. Outset and Defendants Trigg, Ahmed, and Chambers are named as defendants in the Securities Class Actions, which assert claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Actions for these violations of the federal securities laws, the Company's liability will be in whole or in part due to Defendant Trigg's, Ahmed's, and Chambers's willful and/or reckless violations of their obligations as officers and/or directors of the Company.

250. Defendants Trigg, Ahmed, and Chambers, because of their positions of control and authority as officers and/or directors of the Company, were able to and did, directly and/or indirectly, exercise control over the business and corporate affairs of the Company, including the wrongful acts complained of herein and in the Securities Class Action.

251. Accordingly, Defendants Trigg, Ahmed, and Chambers are liable under 15 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of a private right of action for contribution arising out of violations of the Exchange Act.

252. As such, Outset is entitled to receive all appropriate contribution or indemnification from Defendants Trigg, Ahmed, and Chambers.

253. Plaintiff, on behalf of Outset, has no adequate remedy at law.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment as follows:

A. Declaring that Plaintiff may maintain this derivative action on behalf of Outset and that Plaintiff is a proper and adequate representative of the Company;

B. Declaring that Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Outset;

C. Against all of the Defendants and in favor of Outset for the amount of damages sustained by the Company as a result of the acts and transactions complained of herein;

D. Directing Outset to take all necessary actions to reform and improve its corporate

1 governance and internal procedures to comply with applicable laws and to protect Outset and its  
2 shareholders from a continuation or repetition of the damaging events described herein;

3 E. Granting appropriate equitable relief to remedy the Defendants' breaches of  
4 fiduciary duties, including, but not limited to the institution of appropriate corporate governance  
5 measures;

6 F. Awarding Outset restitution from Defendants, and each of them, and ordering  
7 disgorgement of all profits, benefits and other compensation obtained by Defendants, including  
8 profits obtained by insider sales;

9 G. Awarding Plaintiff the costs and disbursements of this action, including reasonable  
10 attorneys' and expert fees and expenses; and

11 H. Granting such other and further equitable relief as this Court may deem just  
12 and proper.

13 **JURY DEMAND**

14 Plaintiff hereby demands a trial by jury.

15 Dated: June 16, 2025

Respectfully submitted,

16 **THE ROSEN LAW FIRM, P.A.**

17 /s/Laurence M. Rosen

18 Laurence M. Rosen, Esq. (SBN 219683)

19 355 South Grand Avenue, Suite 2450

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20 Telephone: (213) 785-2610

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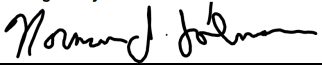
21 Email: lrosen@rosenlegal.com

22 *Counsel for Plaintiff Norman Johnson*

**VERIFICATION**

I, Norman Johnson am a plaintiff in the within action. I have reviewed the allegations made in this shareholder amended derivative complaint, know the contents thereof, and authorize its filing. To those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true.

I declare under penalty of perjury that the foregoing is true and correct.  
5/13/2025

Signed by:  
  
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Norman Johnson